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C O N T E N T S

P R O C E E D I N G S

Open Committee Discussion

DR. PATTERSON: We are starting this morning and, basically most of the day, is on accreditation body standards. We are going to start with the application for approval -- this is on pages 14893 and 94 -- and the accreditation body evaluation which is on 98.

Bob Smith, it's yours.

Accreditation Body Standards-Application for Approval as an Accreditation Body, Accreditation Body Evaluation

DR. SMITH: In an effort to get through this quickly, I don't want any comments.

[Overhead.]

These sections, 900.3, Application for Approval as an Accreditation Body, and 900.5, Evaluation of an Accreditation Body, were really very short. In fact, I think what you will see when Charles Finder presents 900.4 that there is considerable overlap in the comments that will be attributed to 900.4 relating to accreditation bodies in general and their evaluation.

The discussion across these three sections is going to have considerable overlap so I thought that the best thing for us to do is to get through this one quickly and then move on to Charles'. We will help him with that.

There were not that many comments specific to the application. In fact, the application procedures as specified were mostly general in nature and generally, you know, actually positive. The majority of the comments supported the concept of accreditation and a review of an accrediting body's application, in other words, they supported the idea that FDA would scrutinize these applications according to the regulations.

One comment expressed concern about conflicts of interest as states can serve as both accrediting body certifying agencies and inspectors, and essentially this would be a factor in the evaluation of an accrediting body's application as to the degree to which those conflicts of interest can be minimized or eliminated.

Another comment expressed concern about varying standard if an increasing number of states become both accrediting bodies and certifying bodies, and this again is a comment in keeping with one of the underlying goals of MQSA, which was to have a system of checks and balances. It is not that this is impossible in a state, but that it may be difficult to achieve.

Any questions?

All right. Moving on to procedures for performing clinical image review and for performing phantom image

review. Again, there are considerably more comments organized under 900.4, and there were not that many comments specific to this because it had bearing on the application, and as well the desire that an application for an accrediting body would have to specify how they were going to do this.

One comment, however, was critical of requiring an applicant to provide detailed procedures describing the clinical image review and phantom image review, but not specifying the design criteria by which these procedures should be measured.

In a sense, this makes the clinical image review and the phantom image review performance based as opposed to design based, and essentially, that means that there could be a very large black box as to how these things are done.

Another comment recommended that the procedures for image review be provided to all facilities to improve quality and assist facilities in administrative hearings. That to me sounded tantamount to tell us what you need to see to give us approval, and let us know the procedures so that we can defend ourselves if we are cited against them.

This comment, I think really didn't understand the intent of that part of the application.

Any questions?

All right. Next overhead.

[Overhead.]

DR. SMITH: In 900.3(b)(3)(iii)(J), which relates to policies and procedures to assure processing of accreditation applications, this general comment seemed to address previous critiques that the relationship between an accrediting body and the facilities should be run very, very efficiently, and that accrediting bodies should be accountable or have some degree of accountability for meeting certain requirements of communication.

One comment just simply said there ought to be a rule that any communication with accrediting body has to have a response, I mean as if the implication is that you could send a letter to the accrediting body and never hear from them.

So, essentially, I think they were asking FDA to set some measure of timeliness of response to inquiries or requests for assistance.

In the next section, a description of the appeal process. Two comments were general in nature, and one comment asserted that the rule failed to specify standards for personnel. One comment suggested accrediting bodies be inspected against a record of requests for information.

Again, the comments were simply not that specific or prescriptive.

Finally, for procedures for performing clinical image review as organized by the comments, one comment endorsed the concept of this requirement, and that was the extent of the comment.

MS. HEINLEIN: Can we go back to that o ther slide?

DR. SMITH: Yes.

MS. HEINLEIN: The comment that sought the requirement that an accrediting body be required to respond to communication from facilities, is there nothing in here that does say that there should be reciprocal communication from the accrediting body?

DR. SMITH: I think the rules say that, that that is one of the criteria by which FDA would evaluate their performance is to determine that they had actually responded to inquiries.

MS. HEINLEIN: So that the FDA would assess that through documented letters that say we received this letter, here is the response, and they would able to look at the dates from that.

DR. SMITH: Yes.

MS. HEINLEIN: Because I mean I think that that is real important.

DR. SMITH: Yes, there is no question about that. It is just that it seemed to be more reflective of a past experience than the lack of assurance in the rules.

MS. HEINLEIN: Okay. Thank you.

DR. SMITH: The last section in Item (3), any other information that would be required by FDA with respect to approval was just regarded by one comment as too vague and perhaps too open-ended, and felt it should be deleted. This comment in a sense felt that the FDA should have to clearly define what they wanted to see from an applicant from A to Z, and not have any other options to determine information at its discretion.

This other comment on formal notice of approval felt that bases of approval should be changed to basis of approval. I looked that up, and in fact, it seemed to be bases of approval as opposed to basis of approval, but again, they were probably tired when they read it.

Yes.

MS. KAUFMAN: Is that under 900.3(d)(iii)?

DR. SMITH: Yes.

MS. KAUFMAN: Because the actual comment was basis for denial, basis for any denial to bases for any denial? It is not a big issue.

DR. SMITH: I don't know whether that is out of ERG or out of the letters, but the difference is that it was a difference of basis as opposed to bases. You know, take it under advisement. I really can't go on until I speak to legal counsel. It may be an important technicality and probably should be considered in that light.

In terms of scope of authority, this related to the five-year interval for approval, there were four comments. Two were positive, one was negative, and one was general.

Two supported the five-year interval for approval, one opposed a five-year interval for approval on the grounds that it was wasteful, and one comment recommended that FDA automatically extend the tenure of an accrediting body if it fails to notify the program about renewal, which almost seems to be the kind of remark that says if we fail to give you a receipt, you can have your meal for nothing.

None of the comments felt that the approval should be less than five years, and in effect what they felt is if the accrediting body was performing well, you know, that reapplication was wasteful of time and money.

Are there any questions about the application process? Yes.

MS. McBURNEY: On the renewal, what the comment may have been was what we usually term as timely renewal. If a body or someone applies for renewal in a timely manner, and FDA or whoever the regulatory agency has not acted on that by the expiration date, that it would extend until they do make a determination on that.

DR. SMITH: That is an important issue. I am not sure that is what they meant because they seem to be thinking that the FDA would need to notify them in a timely way of when they were due for renewal or when their application was due.

So, for example, let's say that FDA were to require nine months for application review, and the applicant didn't know that, and even if they submitted their application in a timely fashion, would lose their status as an accrediting body because that period weren't there.

It is essentially I think the comment has to be taken in the spirit of the accreditation body needs to know what FDA would require in terms of renewal in every respect, when is the application due and also, as Ruth is saying, be reassured that their approval would come before it expired.

Any questions on the application? Again, the specifics of what is contained in those applications has a

bearing on the review of Section 900.4, and that is altogether a larger issue.

[Overhead.]

DR. SMITH: In terms of evaluation, there were two comments. One was general and one seemed to be a misunderstanding. One comment stated that the requirement to evaluate accreditation bodies should not be carried out through the annual inspection of facilities which have become inspections of the facility themselves other than accreditation bodies.

This comment seemed to feel that the whole point of MQSA was to oversee accreditation bodies, and if you did that well, then, you wouldn't need inspections, and it also felt that the inspection was a route to scrutinizing the accreditation body's performance by identifying facilities that perhaps were not performing even though they had accreditation. This is an old argument, and certainly not the intent of MQSA.

The second comment stressed the importance of establishing evaluation criteria and procedures for accreditation bodies prior to establishing the final rules, and that I think essentially speaks to the issue of what are your goals and how are you going to achieve them. That is a matter of determining your evaluation criteria.

Yes.

DR. HENDRICK: I am confused by your comment because that is, I thought, one of the ways accreditation bodies were to be evaluated is if they were accrediting a bunch of sites that ended up being substandard, as discovered through inspections, that would be an indicator that they really weren't functioning properly.

DR. SMITH: Right, but it is not the sole purpose of inspection, which was the intent of this letter. The letter basically viewed the inspection program as an arm of scrutinizing the accrediting body as opposed to one of the checks and balances of MQSA, you know, that has multiple goals, which is, as you mentioned, one might be that there is a remarkable rate of failure among facilities accredited by that particular accrediting body.

Yes.

DR. D'ORSI: According to the enabling legislation, the FDA has to inspect a certain amount of these accrediting bodies and report to Congress on their findings. Has that been done or what is the status, what is going on with inspection of the accrediting bodies, has any report been made, have any findings been discovered?

MR. SHOWALTER: There is a draft report to Congress. It is about to go to Congress. I don't believe

it has gone yet, but it is about to. That is expected to be an annual event. The data this year is limited to what we have available, and it will be more extensive in the future as we have more data.

DR. D'ORSI: Is it possible to get a copy of that report?

MR. SHOWALTER: Sure. I don't believe there is any privacy issue. Once it has cleared the department and is ready to go to Congress, it should be a public document and we should be able to provide it to you.

DR. SMITH: Are there any other comments on this section?

I did not see any questions that the FDA had about these two sections.

MR. SHOWALTER: I believe that is correct, yes.

MS. FISHER: Ruth Fisher, FDA.

We received comments that perhaps renewal of application was not necessary because the law also provides for an annual performance evaluation.

FDA's question was it might be easier to disapprove an accreditation body at the end of a term more easily than through an annual performance evaluation. On the other hand, we felt that we didn't want to be duplicative and create extra work for accreditation bodies

when we do an evaluation annually. Therefore, we wanted to ask the committee what they felt about renewal.

DR. SMITH: Ed.

DR. HENDRICK: My understanding -- and I haven't read through it all just right this second -- but is that withdrawal of approval is sort of an extensive process, so if problems were discovered on annual evaluation, that, first, there would have to be a decision made based on that, and then the process to withdraw approval would be much more extensive than the process to simply not approve an accreditation application on the next round. Is that correct?

MR. SHOWALTER: Well, that is the issue. It can indeed be administratively more difficult to do a disapproval than it is to simply let something lapse.

DR. SMITH: Procedurally, from a governmental standpoint, what would your needs be? The worrisome thing, of course, is an accrediting body that is always coasting along at a C-minus or a D-plus, and that you need, you actually have greater leverage under reapplication.

I think there is also a problem if you are supporting correction action, and that corrective action process can be abruptly cut off just through the mechanism of a five-year renewal. In other words, you ought to have

greater leverage on the annual basis or equal leverage on the annual basis than the five-year, I would think.

MR. SHOWALTER: I think in principle you do. I think that in practice, just knowing how things work and knowing how disapproval processes work in general, and you have to have cause, you have to have -- in principle, you have all of these things. You know, on the annual basis, you would have them as a part of a five-year or whatever term renewal. Administratively, I think it is more difficult to do a disapproval.

DR. SMITH: Ruth.

MS. McBURNEY: Since this is similar to what we do in licensing, we find that it is easier through the renewal process to get facilities, and therefore, in this case, like an accrediting body, to change some procedures during that renewal review than it is to get them to do it at other times, and if there is an area of concern, I think that during the renewal process would be a good time to get things kind of beefed up in an accrediting body.

DR. SMITH: Cass.

MS. KAUFMAN: I think both FDA and the accrediting bodies are going to be surprised at how quickly five years rolls around, and the application process and your review, I think is going to be very lengthy for both parties.

I would suggest considering increasing it to seven years renewal instead of five.

DR. SMITH: Is there a way for FDA to streamline the process of renewal for an accrediting body that is doing well?

MR. SHOWALTER: Yes, certainly, there is. I mean I can't tell you offhand what it is, but it would at least theoretically be possible to design a reapplication --

DR. SMITH: That builds upon the annual evaluations?

MR. SHOWALTER: Yes, to be contingent on the annual evaluations and to be contingent on what issues you had associated with that body, if any.

DR. SMITH: So that it is only going to be burdensome for those accrediting bodies that have not performed well, but it wouldn't be necessarily an entire reapplication for those accrediting bodies that were performing well.

MR. SHOWALTER: Right, and I don't want to go too far in the direction of talking about how much easier it is to deal with the reapplication, because there is the administrative burden, and that is what we are talking about is how to balance that between needing a reapplication and the reapproval process.

DR. SMITH: Ruth.

MS. FISHER: One thing that we have discussed is that we would not ask accreditation bodies to provide us with materials we already have, not to go through that whole thing, but provide us with new information or updated information.

DR. SMITH: Pam.

MS. WILCOX-BUCHALLA: Pam Wilcox-Buchalla.

The ACR was one of the commenters who said they thought the renewal process was duplicative. Given the discussion today about the fact that you can't do disapproval very easily in that interim, I think we might be willing to change our position as long as we could say that it was a streamlined process that addressed corrective action. I don't see that as a problem. We were more concerned about the volumes of work that the accrediting body has to do in the initial application and the review process.

DR. SMITH: Carl.

DR. D'ORSI: Just a point of clarification. Who inspects the accrediting body through the FDA, what mechanism, person, body, committee, et cetera, does this?

MR. SHOWALTER: The oversight process is multifaceted. We have periodic discussions, visits to

accreditation bodies from our headquarters personnel. Then, the inspection of facilities is done by the field folks who normally do inspections. So, the data comes from a lot of different sources. Any issues that we have, we typically just call and talk about.

DR. D'ORSI: So it is something that doesn't take place at one point in time.

MR. SHOWALTER: It is an ongoing process throughout the year.

DR. SMITH: Ed.

DR. HENDRICK: Just to summarize, it seems like there would be middle ground here to have a different application process for an initial accreditation body application than for renewal, to have the renewal streamlined in the sense of only updating additional information that the FDA doesn't already have, and that might be the best way to handle it rather than trying to depend on suspension based on annual evaluation.

DR. SMITH: Florence.

DR. HOUN: I just wanted to say that actually, Ruth Fisher is in charge of the accreditation body oversight team that is composed of members from other branches besides standards, inspection, compliance, as well as radiation program experts, so there is a team that does the

evaluation, and they do on-site visits, and they are working, it is almost weekly we have contacts with all the accreditation bodies, and sometimes it is daily.

DR. SMITH: If there are no additional comments, probably the most salient part of this review is that I think the will of the committee is that the FDA design a procedure that would make reapplication minimally burdensome or a minimal procedure based upon an accrediting body that is performing well on the basis of annual evaluations, and that it can actually depend upon the reapproval, the five-year reapproval for those accrediting bodies that have not been performing well.

Thank you.

DR. PATTERSON: Thank you, Bob.

We will now move to the Accreditation Body Standards, Code of Conduct and General Responsibilities, and Facility Standards. Unfortunately, Marydale is not here for this, but Charles Finder will be doing the moderating on this.

Accreditation Body Standards-Code of Conduct and General Responsibilities, and Facility Standards

DR. FINDER: First, let me say that I am going to do it from my chair here because I am not feeling that great anyhow, and I don't have any overheads since we got informed

about this late last night, and if everybody here remembers, we were all here late last night discussing other things, so there wasn't much time to do anything else about it.

Basically, we are going to be talking about the comments for standards for accreditation bodies, and this is included in Sections 900.4(a) and (b), and we are talking about pages 14894 and 895.

There were a whole bunch of general comments and then a few specific. I will say that, going through this, most of the comments are one or two people discussing certain issues, although there were a few issues in which there was a significant number of people that did write in.

Probably the best thing to do is try to go through most, if not all, these comments, and try to highlight some of what I think are the more important ones, but we certainly can go through each one individually if you want.

One comment under the general ones was that FDA or the states certifying body should be responsible for the enforcement actions, and not the accreditation bodies, and this is not the only comment that talks about something like this indicating that the accreditation body should not have enforcement abilities or should not try and enforce some of their own rules.

Another comment objected to any one entity having more than one responsibility in this three-part program that they were talking about, and they were trying to say that division of labor is a good thing, and that be separating out these things, you decrease conflict of interest and create a better overall system of checks and balances.

Another comment talked about the lack of requirements for the accreditation body to have a consumer complaint mechanism like there is for the facility. Just briefly, I do want to say that on page 14894, under (x), there is a requirement that the accreditation body describe their consumer complaint mechanism. So, I don't know, it is in a different section, I don't know if it is because they didn't see that or forgot about it when they read that, but there does appear to be some comment about that already.

Another comment was that excessive requirements for the accreditation bodies will destroy the basic concept of the accreditation body, and this is their significant involvement in the public and professional sectors.

Detailed rules will reduce the opportunity for creative approaches and innovative development of new QC tests and procedures. That was that comment there.

Under Section 900.4(a), we did receive well over 100 comments that were printed on identical forms, stating

that FDA should prohibit conflicts of interest by accreditation bodies, and should adopt the conflict provision that was stated in page 14887, which I believe is part of the preamble. Right. If I am not mistaken, that refers to the AMSA proposal on conflict of interest. Is that correct?

MR. GRAVES: That is correct.

DR. FINDER: Thank you. The first column. "Satisfactory assurances that the body does not have any interest in the development, sale, promotion, or distribution of any product (including computer software) under circumstances where the product will be the subject of inspection or review by the accreditation body in facility quality assurance or quality control or other aspects of the accreditation program. This restriction does not apply to educational programs or educational material typically prepared to disseminated by an accreditation body."

So, there were at least 125 comments supporting that.

Also, one comment stated that FDA should not hinder accreditation bodies from performing as independent entities. The comment implied not doing so exhibited a lack of faith in the accreditation bodies, in which case the entire program should be halted.

Does anybody have any comments on those comments?

Okay. Let's move on to 900.4(a)(1), which deals with review of clinical images and other aspects of facility practice.

There was one comment that said the accreditation body shall have the discretion to determine what review is appropriate for a given circumstance as defined in the subsection, and they cited certain concerns. A consideration should be given to realistic time constraints. The AB should have the ability to initiate other investigations, such as random film checks, on-site visits, those kinds of things.

And due to the conflict of interest, they state that in a state, certain people may be precluded from participating in these kinds of reviews.

Again, of the few comments there were, it was that these things should not be too specific to allow the accreditation body to have some latitude in dealing with certain situations.

Yes.

DR. D'ORSI: Charlie, I am a little worried about the criteria of the accrediting bodies for the clinical image reviewers. When you receive these applications from accrediting bodies, do they specifically state the criteria

for individuals doing clinical image review, do you require a certain level of expertise out of individuals doing clinical image review, because this has never been, at least to my knowledge, discussed in this meeting, and I have a large void in that area, and I am very worried, because this is where the rubber meets the road, this is the whole key.

It is nice to have a structure like this, but if your foundation is fault, it is going to fall. So, do you have any specific criteria from accreditation bodies as to who is doing the clinical image reviews, what training they have had, what responsibilities, et cetera? And if you do, can you share that with us?

DR. FINDER: Ruth.

MS. FISHER: Each accreditation body does submit their criteria. They submit the CVs from each clinical image reviewer. The minimum basis is that you must be an interpreting physician, and then you must have considerable teaching experience, performance experience, publication experience on a regional, state, or national level, and so all reviewers are evaluated in light of these.

DR. D'ORSI: Can we have that material? It must be written down fairly straightforward, you know, criteria to meet as a clinical image reviewer. Is it possible to get that?

MS. FISHER: Sure.

DR. D'ORSI: Thank you.

DR. FINDER: Yes, Ed.

DR. HENDRICK: Carl, you might be jumping ahe ad of where Charlie is right now, but it is under 900.4(a)(4). It is in the first column of 14895, under (4) and (5). There is a pretty elaborate specification of what the accreditation bodies have to do to administer the clinical and phantom image review and to assure that there aren't conflicts of interest.

DR. FINDER: I will say that there are other comments from the public that also have the concerns that were just raised by Carl, and I do agree that I personally consider clinical image review as a firm bedrock on which this program is based, so it is very important.

Let's go on to some of the other comments that I think are important. There were some comments on 900.4(a)(2)(i) and a(3) about changing the business days, the amount of time we allow accreditation bodies to perform certain functions.

Under (a)(3), there were six comments that recommended changing "within 5 business days" to the "next business day," and that referred to, "The accreditation body shall inform FDA within 5 business days of becoming aware of

equipment or practices that pose an unreasonable risk of substantial harm to the public." There was also a comment about what was meant by "substantial harm."

Does anybody have any comments about that, whether you believe the 5 days is long enough? Yes.

MS. HEINLEIN: Well, if, in fact, that the accrediting body has become aware of equipment or a practice that poses "unreasonable risk of substantial harm," then, was there a reason that the 5 business days was selected as opposed to the next business day? I mean if this has a potential for causing substantial harm?

DR. FINDER: The reason behind it was, the feeling behind it was that this is notifying FDA, this is not taking action.

MS. HEINLEIN: Right.

DR. FINDER: So, this was not the question of allowing the substantial harm to continue. It was a question about notifying us about it, but the actions would be taken before that.

MS. HEINLEIN: Okay.

DR. FINDER: But I will mention that this comment was actually made in the April meeting also by the committee to change it to "next business day."

Yes.

MS. McBURNEY: Sometimes it is difficult for a body to finish its investigation of such a thing, and perhaps there is a middle ground. You know, if you are not able to reach FDA in that one business day, perhaps, you know, more like 3 or so, somewhere in between there might be more appropriate. There may be circumstances where it is really difficult to do it within one day.

DR. HOUN: The proposal is within 5, so it allows for 3, 1, but no more than 5. That is why it is flexible.

DR. FINDER: Rita.

MS. HEINLEIN: I think when you first read this, it makes it sound that it is not just notifying the FDA, but taking some type of action for the facility that it doesn't continue, but looking at it more closely, if it is just that they are informing the FDA, and they have already taken the action, then, I think that within the 5 days is fine.

DR. FINDER: Yes.

DR. D'ORSI: I am sorry, just one other thing. Are there, to your knowledge, any restrictions on who can use an accrediting body, for example, may I send my films to California to be accredited?

DR. FINDER: You can do that, but it isn't going to work. No, you cannot. For the state accreditation bodies --

DR. D'ORSI: In other words, the states can only accredit in their own states?

DR. FINDER: Right.

DR. D'ORSI: So, the ACR is the only accrediting body that crosses state lines?

DR. FINDER: Yes.

MS. KAUFMAN: That requirement is actually in the proposed regulations, that a state, for example, cannot require a facility to be accredited by their own state.

DR. D'ORSI: But if I wanted to --

MS. KAUFMAN: I know, but I think that is also in here.

MR. SHOWALTER: It has been made a condition of approval of each of the state accreditation bodies, and we anticipate that to be the case in the future. It has not been an issue because no state has wanted to accredit facilities outside the boundaries of their state.

MS. KAUFMAN: I might point out just for the record that in California, the films are reviewed by ACR, so the clinical image review would still take place by ACR.

MS. FISHER: This is also what we had in mind under the section scope of authority in the application. So, under that we can limit what an accreditation body is allowed to do. It also allows for if there should be an

application from a regional nonprofit organization that wants to cover five or six states.

DR. FINDER: Bob.

DR. SMITH: Actually, I just want to take issue with Cass' statement, and I can do it when we come to it, but would you like to wait?

DR. FINDER: Why don't we wait.

Pam.

MS. WILCOX-BUCHALLA: I am a little bit confused about this issue of taking action before we notify FDA. If the accrediting body has no enforcement authority other than giving feedback to the facility, that it is inappropriate, we can't actually take action. So, I don't want that misperception to go on here.

DR. FINDER: Rita.

MS. HEINLEIN: I think that is very important. I mean if they cannot take any action, if they have found equipment or practices that pose unreasonable risk of substantial harm, then, I think that should be definitely changed to the next business day, because action would need to be taken, and that action shouldn't be up to 5 business days after they have discovered this.

MS. WILCOX-BUCHALLA: Just to clarify what I perceive is the scenario here, if we were to receive

notification that there were problems with equipment or procedures, we would investigate and confirm that that actually was taking place and then notify FDA as quickly as possible, usually within 24 or 48 hours.

We would also, at the same time, advise the facility that it is inappropriate, but we cannot enforce that they have to cease and desist, only FDA can per advice that we have received from FDA in the past.

DR. HOUN: My comment is that cease and desist is different from taking other kinds of corrective actions because, as an accreditation body, the statute requires you provide assurances that your facilities are complying with standards, and if not, there is denials, suspensions, revoke accreditation, and those are what I would say would be the compliance actions an accreditation body takes.

MS. WILCOX-BUCHALLA: And we do take those. Even in facilities that have been denied accreditation, we have been clearly told by FDA legal counsel that we cannot tell a facility to cease performing mammography. In substantive harm, that would be the issue. We will take prompt action. I just think the committee ought to be aware of what the limitations are in AB versus FDA.

MS. EDGERTON: Patricia Edgerton, State of California.

One of the things that we do as an accrediting body when we find that there is a situation like this, is we would not only notify headquarters FDA, but we would also notify the local FDA offices -- there is two of them in California -- and in addition, whoever the inspection agency is because there is five different inspection agencies in California, and an MQSA inspector, and we then turn it over to them.

So, we do what we can as an accrediting body, but in addition, we would prompt an inspection with FDA personnel, who can do something about it. So, we try to go that step further, at least we are in communication with that body. They can carry it on, we can't, as Pam said, but we can at least take the next step to make sure that it gets followed up on.

DR. SMITH: Just a clarification on the legal aspects, if the accrediting body revokes or suspends or impounds, I mean with all those things it can do with respect to accreditation, isn't that tantamount under the law to a cease imaging requirement, so that the accrediting body isn't inherently required to tell them, but if their accreditation is suspended --

MR. SHOWALTER: It initiates an investigation on the part of FDA to see if the certificate should be pulled.

A facility technically can practice if they continue to have their certificate but have lost their accreditation. However, that circumstance prompts an immediate investigation on our part if evidence were presented by an accreditation body that an unreasonable risk of injury was present. We would very likely do a suspension without a hearing, which can be done very, very quickly.

DR. SMITH: I think that is probably what is coming out in some of these comments is 5 days doesn't seem very quickly. If you were to draw this out schematically, you know, from a decision tree, probably everybody is interested in how long is there a possibility for unreasonable risk to endure.

Ideally, not ve ry long at all. Within 5 days, if the natural tendency is to always to get around to it within 5 days, or even within the boundaries of what unreasonable is, quite a lot of imaging can occur within that period of time.

So, I guess my recommendation is to sort of draw that all out and try to figure out what is most reasonable for a cease and immediate investigation to determine if the problem really does exist.

DR. FINDER: Joel.

DR. GRAY: I think we have a terminology problem here, sort of like the consumer complaint issue. What would pose an unreasonable risk of substantial harm?

DR. FINDER: As compared to a reasonable risk of substantial harm?

DR. GRAY: What is defined in Item (3) here? Is this an issue where you find out that an interpreter who is reading films is not qualified? Are we talking about risking the life of an individual here? Can you give me an example of this?

MS. HEINLEIN: Excessive dose. Could that be an example? I mean I think you bring up a very good point because if it is something that really does cause harm, then, it needs to be addressed very quickly, but what is an unreasonable risk of substantial harm?

DR. GRAY: Yes.

DR. HOUN: In terms of unreasonable risk, we went through looking at all the level 1's, and some of the level 1's, like an unqualified interpreting physician, maybe a license has expired. It does not necessarily mean you put someone at unreasonable risk because the mammograms were interpreted poorly. That could be an administrative issue in terms of the license expired.

On the other hand, it triggers us to find out, when we get a level 1, such as an unqualified interpreting physician, to investigate further in terms of what is the issue with the license, was it because it was revoked by the state or was it because it is two days expired and the state is late in renewing, which we had states -- I won't mention the state -- where they were three months behind in issuing licenses, so people had level 1's, but we didn't feel it was an unreasonable risk.

So, level 1's trigger an investigation. We have asked the accreditation bodies -- in certain circumstances we will go to them in terms of trying to evaluate whether there is a need to do clinical image review to assess the actual -- if there is a risk in terms of the clinical image quality or interpretation issue that might come up. That is something we would work with the accreditation bodies on.

DR. GRAY: Can somebody describe to me what incident or incidents would pose an unreasonable risk of substantial harm? There must be a hypothetical case.

DR. HOUN: All the level 1's, there could be an unreasonable risk, all the level 1's in terms of dose, phantom image, interpreting physician or technologist don't meet the major requirements. It doesn't mean there is, but that means each one of those -- and luckily, this year, this

round there are like 18 so far level 1's -- are investigated further in terms of is this an issue that really affects the public, or is it an issue that deals with paperwork.

DR. GRAY: So, I think the definition here, the wording used is inflammatory to the public, when the public sees an unreasonable risk of substantial harm, to me that means life, limb, the whole bit. We are talking about paperwork that is not completed, we are talking about a dose that might be higher. I don't see any problem with 5 days in those cases.

DR. FINDER: Ruth.

MS. McBURNEY: Normally, this would not be the case. For a situation like this, it would probably be a situation that would either be one that would be picked up an MQSA inspection, investigation, or a state inspection.

We have had several recent instances over the past year in Texas where a facility had not done QA for several months or QC procedures. There were roller marks on all the films during that time. Phantom images were very low score of those that were taken during the inspection, and in that case, there was a cease and desist issued.

So, normally, it would not be the accreditation body finding out first, and then informing the FDA. It

would usually be the other way around, FDA would know of that situation beforehand.

DR. FINDER: Any other? Yes, Trish.

MS. EDGERTON: An example where an accrediting body would find out about it first -- because Ruth is exactly right, level 1's are the inspection part of it, which is a whole other thing -- when you deny a facility accreditation because of failure to pass clinical image review after up to a year and a half, the way that the rules are written, generally a year, and then you get evidence that they are continuing to work even though they have been denied accreditation, that is real serious, and they have been unable to demonstrate that they can comply with national standards of mammography, and not only have they been told to cease doing mammography by a letter from FDA, and have been notified by us that they have failed accreditation, they continue to operate.

We have had three of those in the last year, so we consider that very serious. They are flying in the face of official letters, and they just really don't care, and their images are terrible, and there is a variety of other things with that, but that is an instance where we would find out about it.

DR. GRAY: Trish, I would consider that serious also, but I wouldn't consider that it poses an unreasonable risk of substantial harm to the public. That is the point I am getting at.

MS. EDGERTON: The woman who has had breast cancer missed by a neuroradiologist, who I was later told was an across-the-room tumor, I think facilities that cannot meet standard clinical image review standards that are on a national basis that the majority of facilities can meet, I think that could be of potential harm to the woman who is getting substandard mammography and could die from a missed tumor. I do believe that very strongly.

We have said before that clinical image review is where the rubber meets the road, as keeps getting quoted here, and someone who cannot demonstrate they can pass that, who continues to do mammography, and has the attitude that I don't care about federal standards, I believe is a real harm. You have got a radiologist who is not taking responsibility, and not meeting national standards for film quality.

DR. FINDER: Marsha.

MS. OAKLEY: Trish, I am behind you 100 percent on that. That is one of the reasons we even got involved with this law, was that kind of attitude. It may have been from

a very small number of facilities, but that very small number of facilities who were involved with whatever number of consumers were involved in that mammogram procedure, that can be substantial harm to those women, and I agree with you on that, and I don't think we can continue to say that by definition, you know, what is it, maybe we all would like to see the definition on unreasonable harm be something more, but as someone who is a survivor of breast cancer, as someone who represents 400,000 women for breast cancer, they would see that as substantial harm.

MS. EDGERTON: Certainly more so than dose. You know, we recognize dose as not that big of a problem.

MS. BUTLER: So, I am hearing that right now the definition of substantial harm is subjective, and it is determined by the accrediting body in this particular section. Are we recommending that perhaps there should be guidelines in place on what this means?

DR. FINDER: Yes. I think we have discussed this with the accreditation bodies, and they are quite reasonable in terms of evaluating these things in terms of what they also believe to be substantial harm.

MS. SCIAMMAREL LA: I think we are going back to the same problem that we have last night. I think substantial harm, the first thing, it is not subjective.

Secondly, the problem that we are going around is because we are going to 1997, and facility compliance with consumer complaint, we don't have a system that the patient have the right to complain about. We will not have information to sustain one way or the other.

I think maybe there are not substantial harm, but if we have good mechanisms in place to know what is going on there. I mean if we don't have that mechanism, I don't think we can have -- I think the reason, there has been a lot of cases that has been missing sending information to the patient about what is going on, that she is a positive breast cancer, and I think -- I don't know, Ruth, how serious, when we are going to a facility, we can't really verify that the patient has been informed, they are informed to complain about whatever complaints that we see from this body is a serious harm. I think we need to have a system in place and be sure that we are checking seriously that component.

MS. KAUFMAN: I think guidelines are very helpful in this regard, but I am getting the sense that there are some members who may want it to be really tied down, and I think that is not the appropriate direction to go because items that you cannot even imagine coming up, come up where you want to be able to take this kind of action.

So, you don't want to be tied into a completely objective list. You do want some flexibility to take action when it is properly considered and it is agreed that this is a facility that needs this kind of action.

DR. FINDER: Penny.

MS. BUTLER: I think I am sort of going along with Cass in this, in that if this is not already occurring, perhaps the FDA should work with the accrediting bodies and develop some sort of guidelines to work on, and with the possibility of leaving it open for the unexpected, as Cass presented.

DR. FINDER: Joel.

DR. GRAY: I would support that, and, Cass, I am not implying that I am not concerned about this, but the problem here I see is a public relations issue. The terminology is used -- and I just went back in the definitions -- and substantial harm or serious risk is not defined in the definitions either.

So, I think maybe adding some definitions and adding some "for example" in there, so the public would understand that we are not talking about an immediate risk of death from what is being done in these offices.

DR. FINDER: Yes, Cass.

MS. KAUFMAN: I thin k the preamble might be an appropriate place for something like that, or in guidance, but I think you don't want to tie it down in the actual regulation.

MS. SCIAMMARELLA: I think there is a lot of frustration, and maybe it is because we are sensitive to be a cancer survival, that is a serious concern. If you don't hear in this committee what is the consumer concern, and for what we started this panel to discuss, is because a lot of things is going on. I think we respect what is going on, the discussion of professional issues, but I think we need to see from this panel that you are concerned about the consumer, and we don't want to have a sensation that this is a protection for professional not to have an form of complaint about this going on.

DR. FINDER: Joel.

DR. GRAY: Esther, I am concerned about that, and I am also concerned about it again from a public relations point of view, because if a lady reads that she can be at unreasonable risk of substantial harm in having a mammogram, that is pretty scary, and I would hate to see what Hard Copy of somebody else could do with that.

DR. FINDER: I think we have heard enough. Carole, last comment.

DR. CHRVALA: Just a very quick comment. We ran into this situation in Colorado before MQSA, and it took a long time for our Radiation Control Division to act, and one of the things that they did, because the transgressions of the center -- it was a mobile unit -- were so significant, was that they -- two things. One, the state issued a letter or a notification in the local newspaper, so that women were informed that this facility was shut down basically, and that addressed the issue earlier, I think, that was raised by California, where sometimes women won't know if a facility is okay to go to.

That was one thing we did. I am not saying that we should mandate that, but it was the only way that we could make sure that the word go out, because the extent of the problem was such that we wanted to shut them down as quickly as possible.

I think that doing such s ort of a newspaper announcement, just like you announce bankruptcies and things like that, was the approach that they took. But I want to say it also took them at least a month to get to that point. Now, this was before MQSA, and we were relying on our Division of Radiation Control to do this, and they had tons of hoops to jump through even though we had substantive data

showing that this facility was subpar in performance on a number of dimensions.

DR. KOPANS: Just a suggestion perhaps to resolve this. Why not change the statement to read "significant violation of FDA requirements"? Isn't that sufficient to shut down a facility?

DR. FINDER: Again, we are getting into the wording here. I can assure you that any word that you pick will start a whole new debate on what that means. So --

DR. KOPANS: Isn't that the law, though? The law is that they are violating FDA requirements, that is why you are shutting them down.

DR. FINDER: That can be taken to mean if you don't, you know, clean your viewbox at the required time, you haven't met the requirement, and therefore we are going to shut you down. It has to be worked on, it has to be looked at, and I don't think this is the forum to try and get the correct wording right now.

DR. PATTERSON: I think FDA has heard and will take under consideration.

DR. FINDER: The next section that was questioned, and we have already talked a little bit about this, is about (iii)(4) where, "The accreditation body shall establish and administer a quality assurance program that has been

approved by FDA," and talks about the requirements for clinical image review, phantom image review, ensure that the clinical and phantom images are evaluated consistently and accurately; and to specify the methods and frequency of training, evaluation, and performance of these reviews.

Yes, Carl.

DR. D'ORSI: Sorry to harp on this. Can I get some numbers? How many or what percentage of the clinical images reviewed in this country are done by the ACR, and how many are done by other accrediting bodies?

DR. FINDER: I can't give you the exact percentage, but I can tell you the vast majority are done by the ACR.

DR. D'ORSI: Ninety percent, 95 percent?

DR. FINDER: Yes, even higher than that.

DR. D'ORSI: Well, let's go the other way around. What accrediting body does not use ACR?

DR. FINDER: The states of Arkansas and Iowa are the only two.

DR. D'ORSI: Is there any mechanism to ensure that those states are reviewing on a standard for the rest of the country, which is basically the ACR, is there any way to get a random sample of cases they review into the -- I guess we can call ACR gold standard, since they do over 90 percent --

to ensure that the criteria that they use are the same, so we don't have a substandard review?

DR. FINDER: Our evaluation of those programs looks at things like that.

DR. D'ORSI: I mean is there any official mechanism that exchanges films to be viewed by the major clinical image review body?

DR. FINDER: Ruth.

MS. FISHER: We have plans to sample from all accreditation bodies on films. We are developing a national plan for clinical image review consistency. We proposed this last year. ACR requested that we have these discussions on final standards before we implement that. We intend to begin work on that in the very near future.

DR. D'ORSI: What are the proposals for this body? Who is going to form this national standard clinical image review body? Are you going to take people from ACR or all the accrediting bodies? Who is going to form this committee?

MS. FISHER: We have a statistician who will be developing how many films need to be sampled and how many reviewers from each accreditation body in order to have statistical significance.

Then, what we would like to do is hold a consensus conference when representatives from the accreditation bodies and their clinical image reviewers come together and review the data. We will not evaluate the data for them. We would like to present it to the clinical image reviewers themselves and have a discussion about the results.

DR. D'ORSI: It sounds if you include the two states in an equal manner on this committee, that don't review that much, it seems a little stilted. If the ACR does 95 percent of the reviews, they come closer to a gold standard than a committee made up of the minority.

MS. FISHER: I don't understand a committee.

DR. D'ORSI: In other words, if you include a clinical image reviewer from Iowa and Arkansas with equal status to a representative from the ACR, that is not equality.

DR. FINDER: Again, now we are getting into very specifics about the proposal, and that really doesn't have anything -- well, it has something to do with the regulation, but we are getting into the specifics of it. But it is being looked at, and it is going to be evaluated.

DR. D'ORSI: Fine.

DR. FINDER: Bob.

DR. SMITH: Where are you exactly?

DR. FINDER: We just finished on (4). We are now moving to (5) hopefully, on page 14895, the first column. Hopefully, we are going to start on (5).

In (5), there are several comments worrying about conflict of interest amongst the reviewers especially within the state.

DR. SMITH: I am sorry. The one thing that we really haven't addressed today is the issue of conflicts of interest, and following back on what Carl was saying, and also in the context of how the program of approving accrediting bodies has I think changed over time in terms of identifying what are the qualifications for being willing to be a clinical image reviewer other than just be willing, the issue conflicts of interest, I think requires more thought than just the state's assurance or the accrediting body's assurance that they have minimized those standards or that they don't believe that those conflicts of interest are real.

One of the things that the ACR has had all along is that radiologists, who are reviewers, clinical image reviewers, do not review films from their own state, and I have thus far not been persuaded that that kind of a conflict of interest can be eliminated simply on the basis

of the assurance of blind review especially in a small state.

DR. FINDER: Assurance of what?

DR. SMITH: Blind review.

DR. FINDER: Oh, okay.

DR. SMITH: So, I guess I would ask you all, or Ruth, as to how you really intend to address the issue of potential conflict of interest that have been raised by a number of comments about the possibilities that a clinical image reviewer would be subject to a variety of pressures of being a reviewer of their own colleagues' work, and being in a position to make decisions that they would pass or fail accreditation.

DR. FINDER: All I can say is that this is a very important topic and has been looked at during the accreditation reviews, and if you want to go into the specific details of how and what we look for -- is that what you are asking?

DR. SMITH: No, I was saying that you have got one accreditation body that determines, that views it as a sufficiently important issue to have rules governing it. You have two others that --

DR. FINDER: -- that also have r ules governing it.

DR. SMITH: But they don't require out-of-state reviewers.

DR. FINDER: Right. So, you are saying that it has to be out of state, otherwise, there will be conflict of interest, that alone?

DR. SMITH: Well, no. I am saying that the American Cancer Society's comment, and I think there were some others, said that out-of-state reviewers offers a protection against conflict of interest, real or otherwise, that is very hard to gauge, but at least the American College of Radiology viewed it as such a serious potential that they determined that you would not have an in-state radiologist reviewing another radiologist's from that state or facility's films.

In clinical image reviews that we have supported, we have observed radiologists identifying the films from a facility even though the facility's identify was masked, so there is always the possibility that not only you can know whose films you are looking at, but also that you may feel, whether you knew this or not, subtle pressures that your colleagues know you are a reviewer, and that decisions you make about their clinical images, you know, will be identified with your decisions.

DR. FINDER: Dan.

DR. KOPANS: I would like to second what Bob is saying. I think with all the assurances in the world, if you are certifying your own state, you have an inherent conflict of interest that is impossible to avoid, whereas, if you are never certifying your own state, you don't have that conflict of interest.

You can have, again, as many assurances as you want, but it is still your state.

DR. HOUN: I guess I haven't seen that. In looking at the performance of Iowa and Arkansas in terms of their failure rates and then when we actually went, Dr. Finder and others went to look at how they were evaluating films, the critique and the concern that these folks have about ensuring that mammography is the best in their state was overwhelming.

They actually -- you can see in some of the states -- were much more rigorous in enforcing corrective actions, as well as going to the facility and making sure that these actions happened in terms of instead of having just written reassurances that these actions happened.

I think that the feeling of because you folks are from a certain state, and you are reviewing the same folks in the state, that that is going to prejudice you, the reviewers from ACR are internationally known, you have a lot

of network with other facilities. The films are blinded in terms of you don't really know what facility this is coming from, but still there is still opportunity that that knowledge of other people's work that you are familiar with is there, if that is the case, I know that you are supposed to turn the films back and say that, you know, I might be prejudiced because I think I know who this is from.

The states also have the similar type of assurances and practices to minimize knowledge of who these people are, if they are colleagues, do not review those people. In Arkansas, they even do it geographically in terms of shipping different films from a particular area to reviewers from a different area.

But I think just the belief that because these people are doing reviews within state, they are going to be inherently prejudiced, we have seen it actually the other way, that their failure rates are higher because they don't want them practicing in their back door.

DR. FINDER: Carl.

DR. D'ORSI: It is not to imply that the states aren't doing a good job, but I think what we are seeing here is part of the problem of lack of communication of these events and results.

For example, we would like to know the failure rate in each of the two states, if that is made public. We never discuss these things that we are discussing today as far as I know in an open forum meeting, and part of the clinical image review is looking to see if the films are labeled correctly. So, everybody knows where these facilities are, because you really --

DR. FINDER: Carl, can I just answer that?

DR. D'ORSI: Yes.

DR. FINDER: The identification of films is d one by staff at the accreditation body. The films that are reviewed are not reviewed for that attribute by the CIR person.

DR. D'ORSI: Oh, okay.

DR. FINDER: And it is totally -- and I have seen them do this -- they stand in the room with the person, with the reviewer, with the name taped over, just to make sure that that person doesn't try and take that tape off. I mean they are very, very scrupulous about this kind of situation.

DR. HOUN: This obviously shows -- I know that there is a lot of things going on in the MQSA program that you folks aren't familiar with, and that we do need to provide you with more updates. I know we were providing you with updates, and they kind of took away from the discussion

of standards, so we were advised not to do these updates, it got too lengthy. I think we are going to reinstitute that.

We are coming out with the congressional report for accreditation bodies, and that can be reviewed with the committee, but at this forum, I think we are trying to get through the final regs.

I think if you have questions -- I mean a lot of people have questions about the program, and they speak to it. If you have questions, please call us up, because we will be happy to provide you with information.

DR. FINDER: Dan.

DR. KOPANS: Again, this is in the regulation, establish rules for conflict of interest, and the only point I would like to make is that I don't think anyone here is insinuating that the states are doing something different, but, you know, we are early in the program, this is going to go on for many, many years, and it is an absolute conflict of interest to reviewing your own state's images.

No matter how nicely they are doing it, and it is working now, I think it just needs to be established that that is an unavoidable conflict.

DR. FINDER: Bob. Last comment.

DR. SMITH: One final point. I think that Dan's point is well taken. This is not to say that there is

collusion or that that is a natural interest to protect the interests of radiologists within states. It may be, Charles, that the rigor you observed was on behalf of your presence. There is just no telling.

But the point is I have personally observed it work the other way. The ACR viewed it as a serious potential cause of conflict of interest, and if they can manage the simple process of mailing films to an out-of-state reviewer, there is no reason why other accrediting bodies couldn't do that.

It may be that you see a great deal of rigor in the first year, and after the first year, that radiologist finds that they are being somewhat shunned at the state professional meetings, and they back off.

The thing is there is a potential for conflict of interest that is easily addressed by an attempt to minimize its risk, the simple process of not reviewing in states.

DR. FINDER: Let's move on to (6), which deals with the fact that, "no accreditation body shall require, either explicitly or implicitly, the use of any specific brand of imaging system or component, measuring device, software package, or other commercial product as a condition for accreditation by the body, unless FDA determines that it is in the best interest of public health to do so."

Again, there were a whole bunch of comments, a lot of which also I guess could also refer to the 125 comments we talked about earlier, about the conflict of interest. Does anybody have any comment? I know this has been discussed quite extensively by the committee.

Okay. Let's move on to (7). Any comments on that? There were no comments on the public from that one. Let's move on to (8) unless somebody has a question.

"No state agency that is approved as an accreditation body may require facilities in the state to be accredited under the Act, only by the state agency and not by other FDA-approved accreditation bodies."

There were some comments about dual accreditation. One comment doubted a facility being accredited by a state agency would voluntarily week accreditation elsewhere, and they thought that this section was inconsequential. I believe that that was a misinterpretation. I think the purpose of this is to make sure that a state can't require the facility to be accredited by that state accreditation body, and there was some rewording that was asked for in the April meeting on this section because I believe at that time, the way that this is worded, it could actually mean that a state could require that the facility be accredited by them and another, you know, if they wanted to have

another body, but at least by the state. I think that the wording changes suggested in April were to make this a little clearer as to what was really meant.

Does anybody have any comments? Carl.

DR. D'ORSI: If you limit, as you said, the states to approve only the states, it really doesn't fit the last part of that sentence, "not by other FDA-approved accreditation bodies."

If somebody in Iowa wants to be accredited in Arkansas, they can't do this.

MR. SHOWALTER: The intent here was to, under MQSA authority, preclude a state from appropriating all of the accreditations within that state, that is, say, California, Arkansas, or Iowa, the three approved accreditation bodies, must recognize approval from the ACR, the national accreditation body, if that is what the facility wants to do and the way they want to get their accreditation.

The way MQSA is written, if a state wants to establish rules for all facilities in that state under state authority, there is nothing that we can do about that or would want to do about that under MQSA.

DR. D'ORSI: Right, you can't touch t hat, but what I am saying is if I lived in Iowa, I could only go to the ACR of Iowa. I couldn't go to Arkansas. But does that fit

the last portion of this sentence, "only by the state agency and not by other FDA-approved accreditation bodies"?

MR. SHOWALTER: No, because the ACR is another FDA-approved accreditation body.

DR. D'ORSI: But so is the State of Arkansas.

MR. SHOWALTER: We could get into language that duplicated what we have under our approval process. We don't see that that is really necessary.

DR. FINDER: Bob.

DR. SMITH: One of the concerns that was raised in some of the comments, and it is relevant here, is there a potential for conflict of interest in that instance. You have gotten quite a few letters saying that an accrediting body should not offer, sell products, that facilities would be compelled to purchase.

In this instance, a facility may feel compelled to purchase accreditation from the state if the state is offering it out of concern that their inspection will be somehow different if they choose accreditation out of the state.

Does the FDA recognize that as a potential conflict of interest, and if so, what would they do about it, or how can they address that issue?

MS. McBURNEY: I really don't think that it is a conflict of interest. We recently did a survey of all our facilities in the state to see if, given the option, would they want to be accredited by the state or remain with ACR, and the issues brought up were not you all are going to be easier on us or if we go with the state. It was a matter of cost, it was a matter of one-stop shopping, only dealing with one entity or two rather than three.

There was not a perception among the facilities that we were going to be any tougher or easier on them if we became an accrediting body. There were just a lot of other issues, not conflicts.

DR. FINDER: Yes.

DR. GRAY: What facilities in Arkansas, Iowa, and California are accredited by the state bodies and what proportion by the ACR?

MS. EDGERTON: In California, we have 950 facilities. Of those, 291 are California, and the rest are ACR, so it is about one-third and two-thirds.

DR. FINDER: Go ahead.

MS. PENTECOST: Pentecost, State of Arkansas. We have 53 with our state accreditation program, and the remainder with ACR.

DR. FINDER: What is the remainder?

MS. PENTECOST: 108.

DR. FINDER: I think Iowa is somewhere about 50-50, something like that, maybe a little less.

DR. SMITH: Are those numbers a function of the fact that many of these facilities had ACR accreditation before the law, and these other programs are recently approved? In other words, under the law, under the interim rules as exist right now, these facilities could become compelled to be accredited by the state unless the final rules are enacted to actually not require that.

MR. SHOWALTER: That is a theoretical possibility. It hasn't been a real issue in any of the states that we are aware of.

MS. KAUFMAN: I think that an equal argument can be made that facilities might prefer not to be accredited by their state program because of concern that state staff is on site, and may have a better knowledge of what their practices are, of being able to determine false information that is being provided, of being concerned that the state would want their facilities to be particularly good, of being concerned that the facilities we inspect are facilities that are loved ones and neighbors and friends are going to, so we want to make especially sure that they are in good shape.

So, I think you can make an equ al argument that they would not want to go to their state program for accreditation because of concern that they know too much about their practices.

DR. FINDER: Can we move on to (10), where we talk about confidentiality issues for the information that has been collected. There were a fair number of comments that did worry about the confidentiality issue and how these materials were going to be kept confidential.

Does anybody have any comments about that?

Okay. Let's go on to facility standards then .

DR. KOPANS: Could I just ask you a question about that?

DR. FINDER: Sure.

DR. KOPANS: It is in the law here, but is it actually enforceable, that you can prevent this information under the Freedom of Information Act or whatever else?

DR. FINDER: That has always been a question, and I believe there is one state at least that reported that under their state law, at least some of this information can be obtained under the FOI request.

DR. CHRVALA: In Colorado, it has to be publicized.

DR. FINDER: In fact, Arkansas is the other one, so there is at least two states. One of the comments was that this may conflict with state Freedom of Information Act laws in Arkansas. All information received by a publicly funded agency for accreditation review is subject to FOI. I don't know where that comment came from, whether that is actually true. It could be just a public comment that he thinks that is true, but we have at least one other state, Colorado.

Yes.

MS. BUTLER: That is a really interesting question, and for my own information, would a nonpublicly-funded organization, such as a college, be less subject to those sort of requirements than, say, an accrediting body, which is associated with the state, which is part of the state?

DR. FINDER: I personally can't give you an answer. Pam, do you?

MS. WILCOX-BUCHALLA: I don't know the answer to that, but I think that as a deemed recognized accreditation body under FDA, we would fall under their agency, and so I am not sure that we can -- I really don't know the answer, Penny. We would like to protect that information as much as

possible, but I don't think we will know the answer until a test case comes.

MR. POTTER: Jim Potter, American College of Radiology. Because the ACR is incorporated in the State of Virginia, they fall under the State of Virginia state laws, and that question has come up, and there is ambiguity in how that would be interpreted, and we are trying to work with the state legislature to give a little firmer answer on that.

DR. FIN DER: Okay. Can we move on to (b), where we talk about facility standards. There, it basically says that, "The accreditation body shall require that each facility it accredits meet standards for the performance of quality mammography that are substantially the same as those in this subpart and in subpart B of this part."

One of the comments said that we should change the wording "substantially the same" to "the same," so that all the standards are exactly the same.

Does anybody have any comment about tha t? Cass.

MS. KAUFMAN: I think "substantially the same" is probably a better route to go because you may one accreditation body that comes up with a better idea than another one or something, and so if you say exactly the same, I that reduces the likelihood of innovation.

DR. FINDER: Ed.

DR. HENDRICK: Recalling the goal of this enacting legislation, which was to create uniform national standards, I would argue the opposite, that we don't want innovation among accreditation bodies, we want consistency and uniformity, and I think it would be better to say "the same" rather than "substantially the same."

DR. FINDER: Ruth.

MS. McBURNEY: I think substantially the same and consistency are pretty much equivalent. We run into this when adopting regulations that are substantially the same as the Nuclear Regulatory Commission. There may be some slight modifications in wording, but you don't necessarily need to hold the page up and read it word for word to meet the intent of the Act.

DR. FINDER: Yes.

DR. SMITH: I would just like to support Ed's comment that it is not hard to specify standards, and substantially the same is not necessary. The idea is to have a common denominator.

That was the goal of MQSA. Unless there is a compelling reason to do it differently, which was a range of the comments in the alternatives, was that these procedures now are pretty tried and true, and they have been worked out

as a matter of collective definition, so there is really no need to say "substantially the same."

DR. FINDER: Cass.

MS. KAUFMAN: I am going to somewhat disagree with Ed Hendrick on the goal of MQSA, because I think he left out a critically important word, and that word is minimum, that the goal of MQSA was to establish minimum standards, not uniform standards.

DR. FINDER: The last part of that was, "The accreditation body shall notify a facility regarding equipment, personnel, and other aspects of the facility's practice that do not meet such standards, and take reasonable steps to ensure that such equipment, personnel, or other aspects of the practice are not used by the facility for activities covered under the statute."

There was one comment on that, and that is the AB should refer enforcement matters to FDA of the state certifying entity as ABs have no authority in these matters. That was the public comment.

Yes.

MS. SCIAMMARELLA: I am sorry, I wanted to ask a question. What happened with -- and this period of time is five years because a lot of the states were restructuring and consolidation -- what will be the provision for certain

states who are providing that, and become a human service agency, and they will not continue to do this service, what will be the provision?

DR. FINDER: Are you saying that if a state accreditation body decides not to continue to be an accreditation body?

MS. SCIAMMARELLA: It is not that they decide. Many states are going to be restructured, and what kind of service they will be providing, and if this happen, what will be --

DR. FINDER: Again, we are overseein g all these state accreditation bodies in addition to the national, and in any accreditation body, there is a significant change in what they are doing or the funding, or the fact that they are no longer allowed to do something. We will know about that, and will take the appropriate steps in terms of making sure -- and there are details in the regulations that discuss issues like that, the steps that should be taken.

Yes, Cass.

MS. KAUFMAN: I agree with the way that this is phrased, and I think the accrediting bodies do have the obligation to suspend or revoke a certificate, their own accreditation if they deem that they have not met this. So, I guess I am concerned about any of their concerns that they

are not a regulatory body because in some instance, they are.

DR. FINDER: That's it.

DR. PATTERSON: Being as it is about 10 minutes of 10:00, we are going to take a 10-minute break. When we come back, I have been asked to change the order of the next two presentations, and so we will start with the Clinical Image Review first, which is Dr. Bassett, followed by the Phantom Image, et cetera, which will be done by Cass, and I understand that that is agreeable with both of them.

Mike has a comment he would like to make.

DR. LINVER: Could I please ask the committee members and consultants to please stay during the first couple minutes of the break for just a very quick announcement.

DR. PATTERSON: We will take our 10-minute break.

[Recess.]

DR. PATTERSON: As I restated prior to the break, we were switching the two, and we are now going to be doing the clinical image review, which is on pages 14895 and 96, and the on-site visits on 897.

Larry.

Accreditation Body Standards-Clinical Image Review, Onsite Visits to Facilities and Random Clinical Image Reviews

[Overhead.]

DR. BASSETT: Some of this is going to be a little repetitious because it was covered in other areas, so that means we can probably go through it faster.

We are going to be covering two areas here. One is 900.4(c) and the other is 900.4(f), and (c) is the Accreditation Body Clinical Image Review, and that is found on page 14895 through 6, and it discusses clinical image attributes, the scoring of the clinical images, selection of images, the reviewers, what do to with abnormals, and corrective measures.

900.4(f) is On-site Visits to Facilities and Clinical Image Review of Random Facilities. That is found on page 14897, and that covers on-site visits in terms of the sample size that has to be accomplished, selection of facilities, the visit plan, and the clinical image review from a random sample of facilities is a short section, but it did stimulate some discussion.

[Overhead.]

DR. BASSETT: On the next page, starting with the Accreditation Bodies Clinical Image Review, the section begins with a discussion of the clinical image attributes that are required, so there were several general comments about this, and as you can see, they were somewhat

contradictory and probably nit-picking starting at this point, because most of this has been discussed before, and we are really just doing fine-tuning.

The first one said the guidelines were too vague. The next one said they were too specific, and should be moved to guidance.

One said the accrediting body should spell out the CIR criteria. I think what they wanted here was to know exactly what to do to pass the image review, and I don't think that is really the intent, it is like giving the answers to the test, because those things are covered here, in terms of the things that are going to be looked at are well covered in this section, and, you know, the answers can be accomplished by doing all the things you are supposed to do to become certified and accredited, and become an interpreting physician, radiologic technologist under the qualifications.

Another comment was that they were consistent with what is generally known in the literature, so that was a positive comment. One said that accrediting bodies had a conflict of interest. We have already covered that. Some said the turnaround time was too long for clinical images.

Then, there was discussion on each of the clinical image attributes. Starting with positioning, a comment was

that it should be rewritten to say that the chest wall should be included on the image, and in fact, that would only be true for xeroradiography, and I don't think that was the intent of the comment, but it really should be left like it is. It was I think done very well.

The next was on tissue exposure. This is a little bit of nit-picking, but they wanted to delete the word "tissue" and use the word "image." I thought it was better just to drop both "tissue" or "image," and just use "exposure."

Someone thought that (iv), (v), and (vi), thought that those criteria, contrast, sharpness, and noise should be deleted because all images have blur and noise, but I think they missed the point there. I think those should stay in. They are important criteria.

The next question was under "noise," is this quantum model, but in fact, it is a little more than just quantum model, it is primarily quantum model. I think it was written quite well, and the "noise" should be acceptable.

I am willing to take any comments during this that wants to. I am just putting in some of my own comments.

In terms of (vii), artifacts, they wanted to add processing as one, and I thought that was reasonable, because that is an important artifact.

[Overhead.]

DR. BASSETT: Then, under identification, there was comments. Under exam I.D., these are the seven things that were listed as being required for identification of the images. Under examinee, I did think they should insert the need for unique identification number. I don't think we should specify what that should be, whether it be the record number for the facility, or the birth date, or Social Security number, whatever they want to use. Different people have different thoughts on that, but there should be something more than the name.

DR. HOUN: The rule says, "examinee identification," and doesn't say name. It says anything you can use to identify the examinee.

DR. BASSETT: I was thinking we should be more specific and have the first and last name, and a unique identifier, because the unique identifiers really don't help if the woman is going around with her films getting second consults and everything, whereas, the name, I think a patient would want their name on the image.

DR. HOUN: I just wonder whether we should specify what facilities should do in law or leave it up to the facility and what makes the best practice sense. I mean most people will have names.

DR. BASSETT: Well, I could leave it open.

DR. KOPANS: I think it should state rather than just examinee identification, unique identification, use the term "unique identification," and then maybe in the discussion of this, you can say identification such as.

DR. BASSETT: I think the problem with that, Dan, is people will just put the unique identification number on it, and they will leave the name off.

DR. KOPANS: I agree that name is a good thing because if it comes to my facility from yours, I don't know the name, I don't know your unique identifier.

DR. BASSETT: I think if you are going to put one, you have to put both.

DR. KOPANS: The concern that Larry has is that if you don't put name, and I would actually say date of birth, you know, Ellen Smith, if she comes to my facility, and I just have a code number that is from UCLA, I don't know that that is Ellen Smith's mammogram. So, there needs to be some identification that is more universal, but you can also, if

the question comes up, you can pin it down to the exact person.

DR. BASSETT: Rita, you have had personal experience where there have been cases where the same patient has been -- I mean we all have --

MS. HEINLEIN: I think it is important to have first and last name, as well as the unique I.D. I have been at other places where we were looking at previous images on whatever, Betty Smith, and I said her breasts are completely different, and it wasn't until we did further investigation that we realized we were looking at a completely different woman. I think it is real important.

DR. CHRVALA: I think multiple identifiers are critical, and multiple even in addition to name and unique I.D., such as adding in her date of birth, because when you start to collect and you look at a wide variety of films. We actually match on six different variables to make sure we have got the right woman. I don't want centers to have to do that, but it has been critically helpful in knowing that you have got the right case.

MS. SCIAMMARELLA: I think we have got no problem with identification of birth and name. One of the issue is Social Security number for some people. I mean that is one of the issues.

DR. BASSETT: I don't think that we want to specify what kind of unique identifier, but at least there should be one.

MS. SCIAMMARELLA: The other issue is epidemiological issues, that sometimes we have difficulties to collect data by race and ethnicity.

DR. BASSETT: This is not in the patient's general information, but on their film, and I know our patients would have a problem if we put their ethnicity on their film.

MS. SCIAMMARELLA: That is a comment for the future.

DR. BASSETT: My technologists told me they would have difficulty, and they didn't want it on there.

My recommendation would be that you do need first and last name and unique identifier, but these are kind of details now. Then, the date, view and laterality, facility --

DR. KOPANS: View and laterality --

DR. BASSETT: Why don't you wait un til we get down to the sticker part, because I know what your question is going to be. This is just what is currently in there. Facility, they are asking for name, location including city, state, and zip, radiologic technologist, cassette and

screen, which is really the same thing, the number for the cassette that contains that screen, and then the mammo unit number.

Now, in terms of the comments on that, there were comments that it was good and not excessive, and another one that it was too specific and could lead to failure. There was concern that requiring these things, and people didn't have them on there, they would fail their accreditation. I don't think that ever happens as far as I know. No one has ever failed, Pam, have they, for identification alone? I think that is not really a concern.

Some felt there was too much information for the flash, and it should be phased in because current flashers could not hold all that information.

Someone thought that laterality, they didn't think it was clear what that meant. So, I just suggested that in parenthesis we might write in after laterality, "right versus left."

Then, there was one request that technical factors be on the films. I know there has been enough discussion about that already, that that should be something that is more recommended than required, because it would lead to favoring one type of equipment over another.

Then the RT I.D., there was a question whether this was supposed to be specific for the facility, which would be initials, or for the nation as a whole. They thought maybe it was one of the ARRT certificate numbers. I don't think there was ever any intent to specifically identify the technologist for the nation. More, it is an internal quality control mechanism. It is probably better just to use the initials, so that the physician will know if there is a quality control problem, which technologist to talk to about it.

Then, unit I.D. There was two that just thought that was a great idea. Of course, that is if you have more than one unit.

Now, stick-on labels, there was one comment that it would allow for more information on the film, and also someone asked, since it inferred that it should be a flash-type label, that if a stick-on -- if the film label didn't show up well on the flash, should they repeat the films. I thought that was kind of a common sense thing that you wouldn't do that, and you could use a stick-on label in those situations.

Dan wanted to make a comment on the issue of whether you should require a flash label.

DR. KOPANS: First of all, I couldn't find actually in here where it says you have to use a flash label.

DR. BASSETT: Right, so I don't know if it is even an issue.

DR. KOPANS: I am a little concerned about the detail of the view and laterality. There are stick-on labels that give you view and laterality that make it actually easier to find a film in a packet because they are on the end of a film.

I think the axillary portion of the breast, this has been a standard convention since before I was born, is to place a radiopaque marker of some kind identifiable in the axillary portion of the film, and that is fine, but I don't think you need to say that it has to be the projection and the laterality, but that should be somewhere permanently affixed to the film.

We use stick-on labels, and quite frankly, they are harder to get off than the flasher once you have stuck them onto the film, so I don't think you have to sub-specify all this detail. I would just say view and laterality needs to be permanently affixed to the film, and there needs to be an identification of the axillary portion of the film.

MS. HEINLEIN: I think that it has been accepted throughout the country that everyone is using with the exception of a rare few LED markers that indicate the view, and that indicate whether it is right or left breast, and putting it in the axillary area.

I think to not keep the focus on that could open the door for more confusion. I think we should just keep it as it is. We certainly didn't receive any comments from the public stating that it was something that they did not want. I think the comment on just specifying what the term laterality means is certainly something that is good, but we certainly haven't received any comments from the public on it, considering view and laterality, and where they should be placed, because I think that has been accepted as the national standard of care.

DR. KOPANS: I am not sure that we know that. I know there are places that label films in different ways. Certainly, the stick-on markers in our area are very common. I don't see that this has to be a law. I can see that you want the law to read that there is permanently affixed to the film an identifier. This is probably going to change over the years anyhow, and I think it is microlegislating.

DR. BASSETT: To answer the national question as to whether it is accepted, reviewing I guess as many

clinical images as anybody, it is extremely rare, and I can't remember a case in the last year where that convention wasn't followed.

I think the reason it is important is not because one method might not be better, but when you get films from another facility, and you need to put them up, you don't want to make the mistake of getting right and left mixed up with the location of the lesion mixed up, and I think that is why the convention is there.

Maybe there are different ways of doing the convention, but I think it has been a step forward to get this standardized, so that when you get films from somewhere else, you really don't make a mistake in orientation.

Would the other radiologists comment because this is not for me alone?

DR. MONSEES: I agree that we should have the same convention, and that we should label the films the same way in terms of marker, as Rita was saying, on the axillary portion of the breast, saying the laterality and view, and the way that it is suggested, for example, in the ACR manuals.

I think, though, that there is room for interpretation about the way the labeling should be done, and in fact, one of the Charlies put in the questions that

the FDA was asking the panel, should they allow stick-on labels, and even though I can't find it in here, could still be in here that it is stipulated that they need to be on the flasher. I don't think it needs to be on the flasher as long as the films are appropriately I.D.'d. I would like to just say that because I haven't found that particular stipulation in here. I don't know if it exists or not.

DR. CARDENOSA: I would like to echo Larry's comment that in reviewing films, I can't recall the last time when there weren't metallic labels to right and left and view in the axillary tail.

Also, the way this is worded here, standardized codes specified by the accrediting body, I think that gives some freedom as to the stick-on label and the flasher. I mean I think there is room there for the accrediting body to specify that.

DR. PATTERSON: Unless I have missed it in here, and I may have, I don't remember anywhere in here that it says it must be the metal labels in contrast to the stick-ons, and I think as far as convention, being identified in the axillary portion, I don't think that it really makes that much difference exactly how it is there as long as it is permanent in some way or semi-permanent.

DR. BASSETT: Carole.

DR. CHRVALA: These are requirements for a screening mammogram, not for additional imaging like ultrasound, or do these apply --

DR. BASSETT: Ultrasound is not covered under this law. Although there are standards for ultrasound that are being disseminated, they are not mandated by law.

DR. CHRVALA: Like a repeat mammogram or mag views, these will all apply, these standards will apply?

DR. BASSETT: Yes, they should apply to all mammographic images of the breast with appropriate labeling.

Dan.

DR. KOPANS: What I would suggest is that convention is that radiopaque markers, because what Elizabeth was saying is true, it really doesn't say radiopaque markers, but the radiopaque markers should identify the axillary portion of the film.

That has been the convention forever, and if you are going to put anything in that, that is fine, but again, I wouldn't -- again, flashers, in my experience, have actually been worse than stickers because they frequently cut off the date, they cut off the name, and so I wouldn't specify flasher/not flasher.

DR. BASSETT: What you mean by that, the flasher may be maladjusted or not appropriately on the image, so the

information would be cut off. Really, the stickers can cut off things if you just put it on the film. Either can happen. A sticker can be placed over a piece of information.

DR. KOPANS: You have to say that -- it says here that nothing should be -- I thought it said here nothing should be hidden, but what I am saying is I wouldn't sub-specify whether it is a permanent sticker or a flasher.

DR. BASSETT: Well, we have to say it is a permanent sticker, whether it's a stick-on label or a flash label, and I don't think it does. Elizabeth, is that the way you see it now?

DR. PATTERSON: Yes , that is the way I see it.

DR. BASSETT: Is everyone acceptable to that? I mean are you happy that it doesn't?

DR. PATTERSON: Yes.

DR. BASSETT: That is the way we want it to be.

DR. PATTERSON: I just want to make one comment to what Carole said. This is basically we are talking under clinical image review, so this would be your routine images, be they screening or diagnostic, but that would not necessarily be magnification views or spot --

DR. BASSETT: I don't think that is true.

DR. PATTERSON: We are talking about clinical image review here.

DR. BASSETT: Oh, okay, I see what you are saying. These are going to be the two films that are submitted, but my opinion is they should be everywhere.

DR. HOUN: Actually, we probably should make it clear that it is whenever the accreditation body does clinical image review, not only in the accreditation situation, but on site, if you are doing reviews, or random.

DR. BASSETT: But I think what Elizabeth pointed out was that since it says it is for the clinical image review, that it is not making it clear that this should be on all films that are performed, which is I think the intent is that the clinical image review is really not done just because there is a clinical image review, but because we want to see what the quality of the images would be.

DR. HOUN: We could mandate that for all films if we want to be more clear. I think this tool of what you check when you review, and because it is open to random selection, kind of makes everybody have to do it the same.

DR. BASSETT: I would feel good if it was required for all films, though.

DR. MONSEES: I think it should be very clear that it is all films, so that it is standard, and I have one other question.

Although I know that interventional procedures are not covered by this, there are images that are obtained during interventional procedures. Are those covered, and if we do like film copies of analog images of digitally acquired images or whatever, and because of the small window, we don't have the same labeling opportunities, et cetera, do we need to worry about that?

DR. HOUN: Right now, because it is exempt, you don't have to worry. When it becomes -- I think we are working on regulations, and we also have to rework the clinical image review regulations, and at that time we can specify what do you want when you review films, when you look at films, where should be the labeling.

DR. BASSETT: So, I think we have ended up with that a permanent label should be on, but not specify if it is stick-on, but that there should be no ambiguity about where the axillary site is. I don't want to see them put view and laterality down on the medial part of the breast.

I don't want to see the view and laterality moved to the medial part of the breast on a CC view or on the

inferior aspect of the breast on a lateral view. That convention, I think should remain.

MS. HEINLEIN: It just says that it has to be permanent, and I think that pretty much covers it. It doesn't specify how they make it permanent. So, I think the way this is written is fine, perhaps with the addition of adding right and left for a better definition of laterality.

DR. BASSETT: Also, it is clear now, everyone understands the intent that was here, so don't forget.

[Overhead.]

DR. BASSETT: Now, moving to scoring of images. Someone said there should be a grading system. Now, I think what was meant by that, there already is a grading system for clinical image review in terms of, you know, for each attribute it is graded according to a 5-point scale usually. I think what they meant here really was there should be some cut-off point where you pass or don't pass, so you get a total added up, and then -- I don't think that is probably a good idea, because -- does anybody have any feeling about it? I think it is probably better not to have that, because you can have a terrible problem with the film, but everything else could be fine, and it could add up and pass.

I would say that terrible problem would not be identification label, it would be some positioning issue or

it was so blurry, you couldn't see anything, but it could be positioned perfectly. Then, you could potentially pass that image if you had enough points, and I don't think that is really what was intended by this law. You really want an image that would give you diagnostic information. So, I wouldn't do that personally. Does anybody disagree?

Then, in the next one, (ii), to specify at least two independent reviewers. Now, to me it wasn't unclear the way it was written, but if anyone wants to look at that.

MS. HEINLEIN: They are saying by at least two, and this says by two or more. They are saying the same thing.

DR. BASSETT: I think they were kind of picky, but if there is really a problem, I think it should be addressed, but to me it was clear how it was written.

Next, (4), selection of images, this is for clinical image review, the regular three-year clinical image review. Someone indicated they should be from a specified time, however, I think the problem of putting that in law is that there are some issues with how big the facility is and what their volume is, and so on, that could be a problem.

There were six, however, commenting on that. In parenthesis at the end is the number of comments.

DR. KOPANS: Just a general comment, actually just thinking back to what Florence was saying, is that these definitions that are being set up are for, as you emphasized, periodic image review.

DR. BASSETT: Right now we are looking at the routine accreditation, clinical image review that the facility knows about.

DR. KOPANS: But Florence has suggested -- and correct me if I am wrong -- that the accrediting body may also come back and randomly -- I heard the word randomly select.

DR. BASSETT: That comes later.

DR. KOPANS: Okay.

DR. BASSETT: That is like the next section.

This is the one that is the routine, every three years, not random, but everybody knows it is going to happen to everybody.

Someone indicated the phantom and the clinical image should be from the same 30-day period, should that be specified in the law? That happens, I think, so I don't think that is an issue either, but they want it specified, I guess.

Then, there was a comment that more films should be reviewed, more than the current recommendation, which

would be two views, MLO and CC of a fatty breast, both breasts, MLO and CC for a patient with the breast composition, which is primarily fatty, and then one from the case where it is heterogeneously or extremely dense, so there is two different sets of images.

Someone is recommending that more be reviewed.

MS. KAUFMAN: I actually think that that is not a bad idea that the facility submit almost a random film instead of the one that they consider their best, and I am not sure how you do that, but there is I know a great deal of concern that the accrediting body is not seeing what they typically produce.

DR. BASSETT: Well, we will get into that when we get a little bit farther down.

Then, there is a recommendation (i), recommending change view to projection. I think that is actually incorrect. They wanted MLO and CC to be called projection rather than view, but in fact, projection is just the direction of the X-ray beam, and the view includes not only the direction of the beam, but the proper positioning, so actually, view is the correct terminology. I mean it is the maneuvers that are done to position, as well, it is just the projection. I think that should stay like it is.

Under the (ii), no exemptions, they recommend there be no exemptions for submitting both an MLO and a CC. In other words, you couldn't substitute a 90-degree lateral for an MLO or some other view, and no exemptions for dense and fatty both being submitted, because they do evaluate different things or they may identify more readily problems in certain aspects of the clinical image attributes. So, I thought that was a good requirement, and I think it kind of is already.

Then, the accrediting body should develop examples of dense versus fatty breast, and I think we have heard that before. I have never understood it because if you are reading 480 films a year, and you don't know what is a dense and fatty breast, I think it is kind of weird, but it comes up.

Then, the (iii), difficult to find normals, in other words, there is a specification here that you have to send a normal exam, and they were saying it may be hard to find normals, you should also allow a Category II, which would be the benign findings.

First of all, I would remove the word "normal," and just make it "negative," because no one uses the word normal in identifying radiologic cases with absence of, you

know, suspicious findings. That would be a negative really. So, I think the word "normal" is not appropriate.

Now, if you use the word "negative," you could include Category II.

DR. PATTERSON: No. If you used the word "negative," that does not include Category II.

DR. BASSETT: Negative, benign findings is Category II. BI-RADS Category II is negative, benign findings, in other words, you don't need further workup.

DR. PATTERSON: All right. But you say "negative" and "negative benign findings."

DR. BASSETT: They want to allow you to include very typical fibroadenomas and things like that, because they are having trouble finding a case that is absolutely no findings, and I don't think there is anything wrong with that.

DR. PATTERSON: Okay.

DR. D'ORSI: Do you want to use the actual assessment category since they are in the regs already?

DR. PATTERSON: Yes.

DR. BASSETT: Yes, I think that is the in tent. That is why I want to change it from "normal" to "negative."

DR. HOUN: Negative or benign.

DR. BASSETT: Right.

DR. HOUN: So, those are the two categories.

DR. BASSETT: Right. They are actually negative and negative benign findings, but they are both negative cases, Categories I and II.

DR. D'ORSI: If you label it as such, then, you might foster use.

DR. BASSETT: If you want to make it consistent, it should be.

DR. MONSEES: About the Category II and about what we are going to get to later, I know it is premature, we haven't been sending mammography reports, and later it is going to say --

DR. BASSETT: We are going to cover that.

DR. MONSEES: But the reason I am bringing it up now is that sometimes it might be debatable Category II unless it is obvious from the report, for example, that it has been worked up before, for example, if it is something that is a finding, you don't want the reviewer to question whether or not --

DR. BASSETT: I think it is definitely preferable to send a negative.

DR. MONSEES: Right.

DR. BASSETT: I guess the reason for this request is you can always find something, I guess. Some people call

everything benign finding. They never have a case they really call negative. Most of us would probably call it negative, most of the people here, but a lot of places, they see anything, even if it is grossly obvious that it is not significant will make it a II.

DR. MONSEES: My point was that later it references reports, but it doesn't say here that with the clinical images you should submit the reports.

DR. BASSETT: We have to get to that, because that is not currently the practice. That is another issue.

MS. WILCOX-BUCHALLA: I would like to suggest that you leave it as just negative in the regs, and in guidance to accreditation body, include negative, benign findings for facilities that don't have a negative image. Otherwise, the complication for reviewers in terms of looking at reports and assuring that appropriate follow-up was done, will inhibit the speed of the review process.

DR. BASSETT: Which would be adverse to the people who want it speeded up. In fact, I think that that was suggested here in this next comment, which was to only allow the facility to submit alternative films if they didn't have a true negative. I think that is probably the best way to do it, so that all made sense.

[Overhead.]

DR. BASSETT: Now, let's talk about there are several people who wanted random images submitted for clinical image review, and this is something that sounds good, but having recently been part of a project where we did that, I did it with Carol Lindfors and Jim Brenner for a project in the State of California, that involved a lot of review of random images. I will define what we mean by that.

DR. FINDER: Before we go into random, there was a question that was raised by GAO, if you want to discuss that now, in terms of --

DR. BASSETT: I thought we would discuss this first and then discuss it.

DR. FINDER: Okay.

DR. BASSETT: What we found in doing this was that there were a lot of problems. We looked at random images from a large number of facilities, and what we found was -- well, first of all, the problem is that the clinical image quality depends on the equipment, the radiologic technologist skills, the processing, and very much on the patient's physical condition, body habitus, and ability to cooperate, and we found when we were doing these random ones, that we all had to lower our criteria, because we didn't know -- let's say we got some motion -- we didn't

know whether it was possible to keep the patient still or it was just a patient who wouldn't stay still, or if it was an elderly patient who couldn't stay still, or if there wasn't enough muscle on the image because they were so kyphotic you couldn't see it.

So, what we found was we continually had to downgrade our criteria in order to account for those situations, so we weren't really using the same strict criteria we would use in a clinical image review where they were selected images, whereas, with select images, I have no problem using the very strictest criteria. If I see a little motion, I mark down for it, and if I see a lot, I fail the case.

With the selected ones, the next problem is how many random ones do you have to have to know that you can it is representative, and I don't think any statistician has done that, but it is probably 20 and upwards.

We have looked at it, and in fact, in looking at 1,000, for some of the criteria we now grade down for, you can only get them in 85 percent of the cases. So, there is a real problem here. With very good technologists, who were doing a really good job, we found that they could only meet some of the criteria in 85, 80 percent of the cases when we took each individual criteria.

So, my question was, if we put the random in as a substitute for selected, would this be a disincentive for facilities to do cases on elderly patients, ill patients, those unable to cooperate. When they call me across the street and say we have got a patient on a bed here, they are not cooperative, can you please do the mammogram as we think there may be an unknown primary. If those images went in, I would be failed immediately.

The other thing is that if you did do it that way, you would not be able to assure that you got an evaluation of the different types of breasts you want to look at, like the very dense one and the very fatty one.

Anyhow, Cass, you had a comment.

MS. KAUFMAN: I guess I am a little confused because I thought that ACR actually had a system for evaluating random images that did use a --

DR. BASSETT: We are talking now about clinical image review on the three-year basis. Every facility has to turn in their images. That is what we are talking about now. We will go on to the other things.

MS. KAUFMAN: No, I understand that, but I thought that they did have an actual criteria for evaluating random images that did use a lower criteria than their best images.

DR. BASSETT: Not to my knowledge. When I get images, I make a very strict evaluation, and if anything is out of order, I don't say it is okay, because maybe that patient was moving. I think if we do that, we are going to never know was that patient moving because they were not cooperative or was that patient moving because the technologist didn't have enough compression, or do I not see enough muscle because this patient was impossible to position because they were standing like this, or is it because the technologist didn't know you are supposed to get more muscle and neither did the interpreting physician who supposedly reviewed the images before they were sent in. That is my problem.

DR. KOPANS: I would like to emphasize what you are saying, and that is that all the criteria that we have developed in the field for optimal mammographic images are ideal optimal mammographic images, and as I said earlier, people are far from widgets, and everyone likes to do random sampling, but that comes from industry where they are printing out the same thing over and over again, and there are statistical measures where you can pull out five cases and know whether you are operating at an appropriate level of quality.

I think, you know, it is interesting, because you have got in the document here, sample size for the number of visits that you have to do, sample size being a statistical term. The sample size that you would need to get an accurate random assessment of a program is about 1,000 women. You can't do it pulling five images.

MS. KAUFMAN: I know it is coming up later in the regulations, but there is a requirement for random --

DR. BASSETT: Well, there is a requirement that facilities submit -- a random sampling of facilities submit images, and I think they have to be from a very restricted time period. That is the way I understand it. We will get into that in a minute.

Anyhow, those are just the comments. Do the other radiologists want to comment on this, who have experience? Barbara, do you have experience? Barbara only does 30,000 a year.

DR. MONSEES: I agree that I think that we sho uld do the best images, and I think, for all the reasons that have been stated, that we should evaluate those, but also there is a certain level of confidence that you get when you look at images that are not good that are sent in, that tells you something about those people who are choosing the images.

If they sent those in, and there is motion and sharpness, or there is some other reason that they are unsatisfactory and need to be failed, I think that with a high level of certainty, you know that somebody is not doing their job there because they did not pick good films, and it tells you a lot about what they know about ideal images if they are going to send those in to start with.

So, I feel much more confident about failing a facility that sends in images that don't meet criteria than looking at an unknown random image where I am not sure what the circumstances were, as you said.

DR. CARDENOSA: I echo what Barbara just said.

DR. BASSETT: Carl.

DR. D'ORSI: I just want to say that it does two things when you send in or request excellent films. One, it ensures, as Barbara said, that the person sending this one knows what a good film is, and two, it also helps the reviewer to have to know what to evaluate. If you are going to send in random films, and they constantly have to adjust their scale, you don't get a standardized clinical image review.

So, I think that that is the best way to do it, is to ask for an optimal film, and then look at it.

MS. KAUFMAN: I will ask my question about when we get to the random review part, about what ACR is doing when they are looking at random images, because it certainly is my understanding that they do have some kind of a system for doing that.

DR. KOPANS: I think that is a random choice of a center, as I understand it. It is not a random choice of images. The point needs to be made from a scientific perspective. You have it in the regulations that random images need to be looked at, but it is scientifically unsupportable.

MS. WILCOX-BUCHALLA: I think we sh ould talk about random film checks when that comes up, but what we are talking about here is setting a standard for comparing all facilities, and you have to have some measure that is comparable across all facilities, and you can't introduce the variables that we have been talking about.

Women are not widgets. So, random film check is not what we use as a basis for accreditation. Even if a facility does not pass a random film check, they are given an opportunity to do corrective action and be reevaluated, because we recognize the compromising effects of choosing a limited time frame and not having the opportunity to choose best films.

So, you need to keep that thought in mind. We are trying to say apples to apples in accreditation decisions versus validation and continuing education in a random film check.

DR. BASSETT: So, I guess we will get back to that other issue, but I also wanted to hear Mike. Did you want to comment?

DR. LINVER: I just wanted to echo again the comments as a clinical image reviewer, I see the need to evaluate initially at least, and as the gold standard, the optimal films a facility can produce for all the reasons that have been stated before. I think that is critical to the whole process.

DR. BASSETT: Rita, do you want to comment from the technologist point of view since some of these are being submitted and selected by technologists?

MS. HEINLEIN: Well, no, I think it says the same. Barbara hit the nail on the head. I mean if you get images that don't meet the standard, then, that says a lot about what is going on with that facility.

DR. BASSETT: Elizabeth.

DR. PATTERSON: I agree 100 percent. You need to know what they consider their top.

DR. BASSETT: What they consider their standard for getting a good image, and hopefully, that is what they are striving for all the time.

DR. PATTERSON: Yes.

MS. SCIAMMARELLA: I just have a question from the consumer perspective. We discussed this, Larry, if we measure how many missing cases there are in the facility when they are doing -- I mean you compare the random with what outcomes. What is the correlation between --

DR. BASSETT: This is a process where you are not really looking to see whether they picked up abnormalities. You want to see if the quality of the image -- you can have the best equipment and the most expensive equipment, and this and that, but if you can't put all that good stuff you have, and a daily quality control check, and all that, if it doesn't translate into the ability to produce quality image, then, it is of no value at all.

So, this is just another way of checking the equipment and the personnel, positioning skills of the technologist, the ability of the way the physicist has set up, the technique factors to produce an image that has enough exposure to see abnormalities, and so on, but it is not actually looking for abnormalities, it is looking for image quality.

MS. SCIAMMARELLA: I know what you mean, but is there a way to extrapolate and compare this with the outcome of performance, as a way to balance or validate how good they are performing?

DR. BASSETT: This is a different issue than that, and I think that many of us believe there is a relationship between getting a good image and seeing cancer. Otherwise, we wouldn't have any of these requirements. But it is not really the same thing as seeing the outcome in terms of quality assurance.

MS. SCIAMMARELLA: But that will be good for the statistician to work on, a certain way to come out, what is the correlation.

DR. BASSETT: Dan, you c an comment on that from clinical trials. You need thousands and thousands and thousands of people to do that.

DR. KOPANS: It can be done. It is just extraordinarily expensive.

DR. BASSETT: We know that there is some difference between trials, and we believe some of it has to do with image quality, but there is no absolute proof.

DR. KOPANS: The Canadian study is showing a 24 percent benefit.

DR. BASSETT: If you could do a randomized trial where you did bad mammography on this one, and good on that one, and see that you got better results, you could find that out, but I can't think of any other way to do it, because there are so many other variables that come into play in these trials that go on.

MS. SCIAMMARELLA: Thank you.

MS. HEINLEIN: Have we gotten to the image management portion yet?

DR. BASSETT: We are now there.

One thing, on (5), for clinical image reviewers, I think we have already covered that. They wanted more specific criteria, training, and also this variability means inter- and intra-observer variability, and I think that is being handled by the FDA. Ruth indicated that there was a program for that.

Under image management, timely turnaround is one of the issues. There was a comment that they thought it should be done within 60 days. I think it usually is. But then there was another comment that said more time was necessary if you needed to do at third review, so by restricting it too narrowly, it could be compromised by problems, such as an abnormality is found, so that has to be

checked, that an image has -- like two reviewers don't agree, so it has to go to a third one.

There is a couple of issues, so I don't know what you want to do about that. I think generally now the recommended time is 60 days. Is that right? Pam, do you know how much variability there is?

MS. WILCOX-BUCHALLA: In terms of our turnaround time, we are consistently under 60 days now for routines, but as Larry mentioned, if there is an abnormal that needs confirmation, we hold onto the films until the facility follows up, or if there is a third opinion required, it may take more than 60 days, and I am concerned about the 60-day time constraint in regulation that would not allow for that flexibility.

DR. BASSETT: I guess in summary of this whole section, I think things are written pretty well the way they are.

Rita.

MS. HEINLEIN: I have one question concerning (ii). It says if they identify an abnormality on a clinical image, and this finding is not clearly specified on mammography report submitted with the clinical images.

DR. BASSETT: Right.

MS. HEINLEIN: I was going to ask about that. I mean do they submit mammography reports?

DR. BASSETT: Yes, we are getting to that.

MS. HEINLEIN: I am sorry, I thought that is where we were.

DR. BASSETT: That is a good point. I think maybe we should address it now. The way that is currently written, it implies that a mammography report has been sent with the images, and I don't think that is currently the standard way that is done.

MS. HEINLEIN: Th e way this is written, they will have to supply the mammography report.

DR. BASSETT: I am only guessing, but I think the way it was really intended, Rita, was that if an abnormality was seen, then, it has to be checked to see if that was identified on the report.

MS. HEINLEIN: Well, if they are not to send the mammography report along with the clinical images for clinical image review, then, I think that --

DR. BASSETT: It should be written a little bit differently.

MS. HEINLEIN: -- portion of the s entence should be deleted.

DR. BASSETT: So, the question is, is it the intent to require the report to be sent with the images.

MR. SHOWALTER: And I think the answer is no, it was not routinely intended for that to be the case, but in the case where a facility could not come up with a normal, and submitted a set of images with findings, that it might be the case, and I don't know what the current practice is, but it might well be the case in that situation where the report would accompany the images.

DR. BASSETT: Or if an abnormality was identified that the facility had not recognized, that you would want to check that report, request the report, check with the facility and see that it was indeed identified, and not missed.

DR. HOUN: That is the intent of the regulation. It is under exceptions in terms of the 60 day, as Pam was saying, and one of these exceptions is if the reviewer finds an abnormality, and this finding is not clearly specified in the report. It doesn't mean that the report was submitted, but there is going to be checking to see if that was interpreted as normal or abnormal if the reviewer finds an abnormality.

MS. HEINLEIN: Right. But the way it is worded right now, it says that it was not specified on the report that was submitted with the clinical images.

DR. BASSETT: That was commented on in comments, and I think it needs to be rewritten, so that it is more representative of what actually happens. I think we all understand the reason for it, but it is confusing, to one person at least.

[Overhead.]

DR. BASSETT: On the next section, which is accrediting body on-site visits and random clinical image review -- Charles?

DR. FINDER: Before we get to that, we did want to raise the question of the concern that GAO had, and their question on this was about whether they felt that two exams were enough to adequately evaluate a facility, and if the eight attributes were enough.

DR. BASSETT: Well, in terms of the attributes, I think the eight attributes are enough, because they cover the whole gamut of what you can see on a clinical image. That part, I think is easy. Does anyone know of any attributes that are missed, that are least accepted?

I think the attribute part is easy. Now, the question is are two enough, and we will have to throw that out to the group.

DR. KOPANS: It is either 2 or 1,000.

DR. BASSETT: I think we are talking here about selected images, so rather than random, I guess the question is do you want three, do you want four?

MS. HEINLEIN: I think two is en ough. I mean the facility, they are selecting these two saying these are the best, this is our standard of excellence, and certainly, I mean it is like Dan said, sure, if you could look at 1,000 of them, that might be better, but I think that they are -- I think two is enough because they are giving the facility the opportunity to pick and represent their very best work.

DR. BASSETT: I think it puts it better in perspective, too, to understand that about 30 percent of these are not meeting those criteria in terms of passing, so this shouldn't be looked at as something where everybody just picks their images, and everybody passes.

This is really identifying problems, and I think, over time, even the standard is rising because the image quality has improved since this process has been going on throughout the country, and there is still about a 30 percent rate there.

So I think, you know, if everybody was passing, I think I would say, oh, here is problem because everybody is just turning in a good image and all the rest are terrible, but in fact, 30 percent are not passing.

MS. KAUFMAN: A comment and then I guess an issue. First of all, let me say that I can speak for Los Angeles County, and that every facility that has failed the clinical image review has truly been a facility that I have been concerned about and that I thought would not pass, so I think in that regard, it has been very effective.

I think there are a few facilities that I thought wouldn't pass that did, but mostly it really does seem to be working. But I just wanted to mention that a concern that I hear frequently from across the country is that when you are only looking at their best images once every three years, can they go for the last three years and pick out -- you know, they have three years to pick out their best films, and so once there was a discussion about putting in a time frame, and also I think it is a GAO issue, too, about maybe having more than two.

DR. BASSETT: Does anybody else want to comment on the two not being enough?

DR. KOPANS: I think it is important for people who maybe don't do mammography to realize that the criteria

that are being used on this image review are very strict, very difficult to meet, because of variability among patients, so you may have a perfect MLO in the right breast, but, you know, she has got a problem with her left shoulder, and she couldn't get it into the machine, so the left isn't perfect. It is actually very hard even for facilities that are constantly trying to do better and better work to select our perfect images.

So, we are talking here about pretty much perfect images.

DR. BASSETT: If a facility is really conscientious, this is also a very educational process because the technologist and radiologist should get together and evaluate all these things, and look through the cases, and they begin to see how many are really -- you know, by going back and looking at them -- they have to look and see if they are meeting this criteria.

So, at this present time, I think it is working, and I think the GAO would be reassured by the feedback of the conversation we just had.

Now, this is a different issue, on-site visits -- yes, Barbara?

DR. MONSEES: I am sorry to introduce another complication, but I learned from Rita the other day that

some facilities are hiring people to come in as "consultants" or whatever, and take images, and then submit those images when their technologist may not be able to produce good images, and I am very concerned about that.

DR. BASSETT: I don't know to wha t degree that would happen, but I would say anyone who did that would be breaking a federal law, and you have an obligation to report that. It is not? Okay.

DR. MONSEES: Well, is it breaking federal law, because if it isn't -- can we say in here, it says here that the images produced by the facility -- can we stipulate or can the FDA stipulate in its rules that it be produced by a technologist who is listed as one of their full-time employees or whatever it is, so that this cannot happen?

DR. HOUN: Th e other issue is not only produced by, but the images are submitted by, because then the consultant can pick out of, you know, 1,000, which ones you did good.

DR. MONSEES: I think we need to put that in here.

MS. HEINLEIN: And to add to what Flo said, I mean as a consultant -- who, by the way, does not do their positioning and submit their images -- I will often have people say can you look at these images, and what do we submit, and I will say to them, I can critique your images

with you, but I certainly can't tell you, you have to decide what to submit. So, that would help all the consultants out there to say I am obligated by law, you know, you have to pick these images, because they will say you really know what they are going to look at, can't you tell me which ones will pass.

DR. KOPANS: I think the way to deal with who the technologist was is that it has to be a technologist who is certified within that facility under MQSA.

DR. BASSETT: Well, who is performing images within the facility, because they could have one come from one of their other facilities that is better, you know. They have to work in that facility, because you could take one person and have them go around and do all the ones in your practice. They should really be working in that facility. I think that should be included.

I think it is important. Does everybody agree it is important?

[Affirmative responses.]

DR. BASSETT: Because where there is a loophole, there is a way, I guess, and most of us wouldn't think about it.

That is an important improvement, then, from this discussion.

Flo and Charlie, you understand the intent of what they want to change here, so you can handle the proper way to write it.

DR. FINDER: We can certainly look at it and try to figure out a way to do that.

MR. SHOWALTER: What I would say is the goal is that if someone brings in an individual from the outside to do imaging, that it is not representative of what goes on in the facility, and that that should be a violation.

DR. BASSETT: They spe cifically wanted the clinical images that are submitted to be performed by a radiologic technologist who works in that facility, and is listed in that facility as their personnel, and also that they be reviewed by an interpreting physician who is one of the interpreting physicians who is certified in that facility, works in that facility.

DR. FINDER: I would just say I think it is going to be a lot of thought that has to go into this, because I can imagine a situation where you have got multiple facilities that are all under the same ownership where their techs rotate. We don't want to disallow that. We have to be very careful in how we address this, and I don't think -- by trying to fill one loophole, I don't want to create a huge --

MS. KAUFMAN: You can just say that a facility cannot use a consulting technologist to perform the images or consulting interpreting physician to select the images that are used for clinical image review.

DR. FINDER: And then we have to define what a consulting is.

DR. BASSETT: That is why I want to leave it up to you.

DR. FINDER: Because then you are starting to get into contracts and who owns what, so it is very difficult. We will look at it certainly.

DR. PATTERSON: Let them look at it, and not try to write legislation here. I think they have got the message of what we want. We want the people who are listed on that facility to be involved in the clinical image review process.

DR. BASSETT: And once that is in the law, then, when situations like that occur, then, the appropriate thing is the consultant has I think a responsibility to pass it on to the accrediting body, would that an appropriate avenue? What if a consultant comes in, and they ask him to do that?

DR. HOUN: If the facility asks them to do it, the consultant should know by law not to do that, and can report them either to FDA or the accreditation body.

DR. BASSETT: On-site visits is next. We will get to where you select the sample size, but this is where the accrediting body makes a visit, and I believe this was intended to be not the inspection, but a visit to a facility either as a random sample or because they are aware of problems at that facility that have been communicated through consumer complaint or some other mechanism, such as we just discussed, or a consultant might have a concern, or any concern that is passed on may lead to an inspection.

DR. PATTERSON: Larry, I would like to interrupt you at this point. They have asked to take three seconds between the two times, and I will let you go ahead, Charlie.

Special Presentations

MR. SHOWALTER: We have our own little ceremonial event here, and we would like to recognize Mr. Joe Levitt, who is the Deputy Center Director of CDRH, who has some presentations to make.

MR. LEVITT: I apologize for the interruption. I hope it is for a good reason -- it is certainly for a good reason.

Yesterday, I failed to introduce myself. I apologize for that. For those who don't know me, my name is Joe Levitt. I am Deputy Center Director. I have really had

the privilege of being involved with this program from its inception.

What we would like to do is we have several presentations we would like to make today in recognition of the fact that a number of committee members will be rotating off including our esteemed Chair.

There are really three parts. I want to start with Dr. Patterson. I apologize that there is a little bit of embarrassment in this, but with good work comes your time for a little bit of embarrassment.

I have two presentations for y ou, Dr. Patterson. Dr. Patterson will remember when she first got selected to be Chair, she came down one day and we had lunch, Dr. Houn and Dr. Patterson and I and a few others had lunch at one of Washington's finest, was it not, Dr. Patterson, the House of Chinese Chicken. And we knew from that point forward that we would have to make that up to you someday. I have two things for you.

The first is from Dr. Kessler, and is the Commissioner's Special Citation. Now, for those of you who are not familiar with the FDA culture, this is the highest award that the Commissioner has to present to somebody that has worked with the FDA. It is very coveted. It comes with something called the Harvey Wiley Medal. Harvey Wiley was

the first Commissioner of the FDA back in 1906, when the first Pure Food and Drug law was passed. And to give you an idea of the history, the medal that comes with it was done for Harvey Wiley's 80th birthday in 1924. So, this medal has been issued only a certain number of times, and has come down through the ages.

The letter from Dr. Kessler reads: "To Dr. Patterson. It is my pleasure to congratulate you on your selection to receive the Food and Drug Administration's Commissioner's Special Citation.

"The Citation of your achievement reads, 'For distinguished leadership, outstanding contributions, and exemplary dedication, the improvement of mammography services for the Nation.'

"You have been chosen for this award because you have provided invaluable assistance to the FDA. To be selected for special recognition should be most satisfying since accomplishments such as yours impact the well-being of the public. I extend my personal appreciate for your contributions.

"Sincerely yours, David Kessler, Commissioner of Food & Drug."

[Applause.]

MR. LEVITT: This comes with the letter, with the certificate, and for the desk, it also reads, "Commissioner's Special Citation presented to Elizabeth Patterson, M.D., 1997."

And the infamous Harvey Wiley Medal, which stands up right like that.

[Applause.]

DR. PATTERSON: Thank you, and I am speechless.

MR. LEVITT: Continuing, the staff in the Center, while having full faith that the Commissioner would do his thing, did not want to simply sit back and let the Commissioner only do his thing. So, from Dr. Houn and the staff, and all of us in the Center, we also have for you a special gavel presented, and it says on here, "To Elizabeth A. Patterson, M.D., Chair, National Mammography Quality Assurance Advisory Committee, 1994 to 1997."

DR. HOUN: And we paid for all those letters.

[Applause.]

DR. PATTERSON: Thank you.

MR. LEVITT: That was Part 1.

Part 2. We also have certificates for each of the committee members who are rotating off. Each of them come with a letter also from Dr. Kessler. I will read one. They are all identical.

The first one is to Penny Butler. "Dear Ms. Butler: I would like to express my deepest appreciation for your efforts and guidance during your term as a member of the National Mammography Quality Assurance Advisory Committee in our efforts to base regulation upon the best available scientific data and judgment. The Panel has served as a source of assistance and advice of the highest caliber. As you will recognize, it would be difficult, if not impossible, to assemble on a wholly in-house basis the experience, knowledge, and varied backgrounds and viewpoints that are represented on the committee.

"In recognition of your service for the Food and Drug Administration, I am pleased to present to you the enclosed certificate."

And it has a certificate that looks like this. I have one for you. I will read the names and I will walk around to save time.

One for Kathleen Kaufman, Cass Kaufman. Cass is not your official name, is that right?

MS. KAUFMAN: No.

MR. LEVITT: One for Ruth McBurney. For Marsha Oakley. For Amy Langer, whom I see was not able to be here at the moment. And again for Dr. Patterson.

Again, thank you to all of you.

[Applause.]

MR. LEVITT: Finally, I feel a little bit like the wizard in the Wizard of Oz, who at the end says I don't have anything in my bag, but I also want to extend a special thanks to the consultants to the committee. I am including those that were members and continuous consultants in order to stick it through and finish the work on the regulations, we are all indebted to all of you, as well as to our invited guests who have been willing to come and spend several days with us here in Washington working on all the details of these important regs.

So, again, a special than k you.

[Applause.]

MR. LEVITT: And, finally, I would be remiss if I did not also a special thanks to Dr. Houn and to her entire staff especially as we fondly refer to them, "The Charlie's," but also to all the members of the staff that have worked so hard to help make these meetings useful, productive, and the regulations coming forth.

I can tell you sincerely from within FDA, the mammography program is very much viewed as a model program. It is something that is viewed that heralds high quality, and it is something that is really having a major impact on the well-being and public health of women in America, and it

is really the women of America from which all this thanks really comes. The rest of us are simply carriers of that message.

So, again, thank you to all of you. Again, to Dr. Patterson, who has served so well as the Committee Chair.

With that, I will turn the podium back to Dr. Bassett to get back to the work at hand.

DR. PATTERSON: Thank you very, very much.

[Applause.]

DR. PATTERSON: I just have one comment. See, all you guys that are stuck on for another year, what you missed.

Accreditation Body Standards [Continued]

DR. BASSETT: Next, we were talking about on-site visits, and let's go through the comments now.

Now, these, as I mentioned, are the visits that occur either as a random selection, which is required by law, for the accrediting body to visit, do an on-site visit to facilities randomly and also to facilities where there are recognized potential problems or there have been complaints or significant other issues.

The comments are, one, they are unnecessary.

Two, now this one had 16 comments, and I think we have to address it. There was a question. I think what

they are identifying here was what they perceived as an inconsistency in the law or in the way the FDA had written up the proposed regulations.

If you turn to page 14888, in the third column, first paragraph, it says that, "FDA disagrees with the comment that all clinical images submitted by facilities should be selected completely at random."

Then, they make a comment that if random clinical image review is not effective, why are random visits, so it is just they caught some inconsistency here. But I really don't know that they are inconsistent. I think they are totally different issues.

At any rate, that was brought up. Did you want to comment on that, Ed?

DR. HENDRICK: Yes, there is a difference in that what my understanding is when a random site visit occurs, that the clinical reviewer who goes on that site visit pulls a minimum of 10 cases, not just images, but cases, which would be a minimum of at least 40 films, and reviews those in the site visit, so it is not equivalent to looking at a single case.

DR. BASSETT: Right, and it is not equivalent to the routine evaluation that occurs.

DR. HENDRICK: Right, it is much more extensive, and it includes some other components that can't possibly be assessed like on-site evaluation of the QC and physics, and taking a phantom, things like that.

DR. BASSETT: B ut it does show that people are going through with a fine-tooth comb to find something wrong.

Now, accrediting body, in the very beginning of this on-site visit introduction, it is requesting three copies of a summary of all the reports of the on-site visits that occurred that are given by the accrediting body to the FDA, and there was a question about if this wasn't excessive. So, I just had to report that. So, you might want to think about getting your own xerox machine or something. I don't know what it means.

Cass.

MS. KAUFMAN: I am not sure if we are there yet, but I am getting confused because I think we need some clarification about what this random means.

DR. BASSETT: We are going to do that when we get down to the sample size, and I think at this point we will have to go back and look at that question.

MS. KAUFMAN: Okay.

DR. BASSETT: So, the next thing is that someone indicated they should require a five-day notice. I don't think you really want to do that because some of these facilities are those that are at serious potential risk, or whatever that term is, and you probably wouldn't want to give that much notice in those cases, so I think that should be left to the accrediting body.

Now, in terms of sample size, I think here is where we have to go back to that issue. If you go into the original law -- and I had to get some help with this -- it states that -- if you look in Section --

DR. PATTERSON: It is page 3550, under the statutes.

DR. BASSETT: Under the original statute. I do n't know how to identify that page.

DR. PATTERSON: The pages are up at the top.

DR. BASSETT: Okay. If you look at that it says that, "The Secretary shall establish standards for accreditation bodies including standards that require an accreditation body to perform: one, a review of clinical images from each facility accredited by such body not less often than every three years, which review will be made by qualified practicing physicians.

"And, two, a review of a random sample of clinical images from such facilities in each three-year period beginning October 1st, 1994, which will be made by qualified practicing physicians."

I think this is the one Cass is talking about. Now, I went back and I asked people who were there at the beginning what does random mean, does it mean that the accrediting body should take a random sample of facilities and request from them images, or does it mean random images should be taken from every facility accredited, and I think that is the question.

I asked Bob if he co uld comment on it. Do you want to comment? I asked you about it because I didn't know. You were there when they wrote the law. I was involved at that time in talking to congressional meetings, and so on, but I wasn't there when they actually wrote this down.

DR. SMITH: My recollection is that the intent was a random sample from facilities, not every facility, but from the facilities that the accrediting body accredits, because what that would be in effect, would be duplicative of the annual clinical image review. You could actually just amend that and only make that a review of randomly selected clinical images if that was really the intent.

DR. BASSETT: So this not really totally clear, I think, to anybody.

Cass, do you want to comment?

MS. KAUFMAN: What Bob is saying is what my understanding was, too, that it was a random sample of facilities, although it is that, also, or could be that, but it was also a random sample of their clinical images, not the best images, and that is where I am getting confused because then I thought that ACR did have a different review process for those random clinical images, that was less stringent than the best images.

DR. BASSETT: I would have a problem with that from a philosophical point of view, because if you had them meet these very strict criteria, and then you ask them midpoint to send me one set of images from anytime on the day of June 1st, 1996, and you got these images that weren't as good as the ones originally submitted, but you would say, well, the criteria aren't as strict now, so we will accept them even though they wouldn't have passed the regular clinical image review.

I think that is what we are setting up, and I can't believe that was the intent. Does anybody else want to comment on it?

DR. MONSEES: Are we talking about site visits here?

DR. BASSETT: No.

DR. MONSEES: Because site visits, it says on the top, and I wasn't sure.

DR. BASSETT: I am sorry. What we did is we kind of in doing that going into this other issue, which is in addition, there is a random clinical image review that is in the law, that I think I am hearing that everyone understood that to be that randomly you could be selected to have to send in clinical images that are specified from a particular time, and you would want to narrow that range of time. You wouldn't want it to be from a three-month period, maybe from one day or something.

So, you would have to send those in. This would be a double-check to see if the facility was really doing the quality work they are supposed to. Now the question is should you just have them randomly select images or should they again submit the ones they think represent the best work. That is what I think we are discussing.

I would say philosophically that you would want them to send the one that you would rate the way you did the original work, otherwise, you could say this isn't as good

as what they said they did, but I am going to accept it because how do I know the patient didn't have a problem.

MS. KAUFMAN: I think we probabl y need a legal interpretation because I had always thought what I thought, which is what Bob thought, but now that you are bringing this up, maybe we have interpreted it --

DR. BASSETT: Actually, Bob didn't think that. I asked him that specifically. He said he thought they would be submitting the same criteria images, but the randomization would be that the facility didn't know they would have to do that. Theoretically, that would require -- all facilities knew they would be subject to that, and that was supposed to be what was one of the incentives to continue to do excellent work, and also to make sure the excellent work was being done.

So, I don't think that is what Bob told me when I asked him. Ask him. He is right here.

MS. KAUFMAN: Well, I mean I think they could still pick their best images, but it would be over a narrow gap in time. They couldn't go through three years worth of work.

DR. BASSETT: I think that is what is done. Now, can I ask for clarification on that from the ACR, because I haven't asked. Pam, do you want to clarify that?

MS. WILCOX-BUCHALLA: Random film checks for ACR are films that are to be selected from one day's work. We choose the day. Reviewers are aware that there are random film checks, and therefore may be compromised by the patient population for a given day, but there is also recognition that it will not cause their accreditation to be revoked. So, there is that thought process, wouldn't you say, Larry, when you do a random film check, you want to hold them to the standard, but they are not going to be revoked, so if they don't pass that evaluation, they have an opportunity to do corrective action and demonstrate that they can do it.

There was something said a little bit earlier about the time window. They don't have three years to select the films that are their accreditation films. Those have to be selected from in a 30-day period that is current.

MS. KAUFMAN: But that policy doesn't cover every facility that is accredited, because it is relatively new, like the last year or two?

MS. WILCOX-BUCHALLA: No.

MS. KAUFMAN: Your regional facilities --

MS. WILCOX-BUCHALLA: '87, '88, '89, that has been in place since 1990.

MS. KAUFMAN: Okay.

MS. WILCOX-BUCHALLA: So before the law went into effect, it has been a requirement that the phantom clinical and processor have to be from the same 30 days, since you can't shoot the phantom until you get it from us, it is current, always current.

DR. SMITH: Just to follow up on Pam's point, the decision to modify the accreditation program was made in the context of a meeting that took place between one of the subcommittees of the ACR/CDC cooperative agreement, and it was a physics subcommittee where people essentially said, you know, there is some inherent logic to have the phantom image and the clinical image come from a relatively close time span.

This issue of random clinical image review grew out of concerns that are oftentimes expressed, sometime during a three-year period, you ought to at least do one good image. This sort of thing ought to safeguard against those facilities by defining a narrow window of time, ideally a very narrow window of time, from which facilities have to submit images.

It is a quality control check more than an enforcement check, as Pam mentioned.

DR. HOUN: I just wanted to bring up some discussion points about it is a quality control check, I

guess, for how accreditation is doing, if, in fact, the facilities that are accredited meet those image standards and are continuing to meet them.

It also, I think, has a public health benefit in that it reassures women that when they go into a facility that has been accredited, that it continually can meet these standards, and not just on 30 days picking the best fatty breast, so I think there are two reasons why random clinical image review is important.

DR. BASSETT: On that topic, there was another comment. I didn't really want to stay on this because we still haven't finished on-site visits, but there was a comment that ACR thought there should be -- that fatty and dense had to be, you couldn't hold them to that since it is a narrower frame.

The regular clinical image review, where they have a wider frame, they have to submit one that is truly heterogeneously, extremely dense, and one that is either completely fatty or fatty with some scattered islets of fibroglandular tissue, but when you narrow the frame down, you may not be able to submit both of those.

So, their request that that not be required.

DR. HOUN: I can see where if you a re doing a spotcheck for how your accreditation program is doing, you

may just want to select one film from that day. If you are trying to use this as a tool, let's say you get a complaint from another radiologist that the comparisons from this facility were terrible, and then the accreditation body directs that facility to submit, do you think one film is an adequate check?

DR. BASSETT: I thought that what would happen there is an on-site visit.

DR. HOUN: I guess I would want to leave some flexibility in terms of what tool to use, and if we use the mail-in random check for directed investigation of a problem, maybe that standard should be a little bit higher than the quality assurance check.

MS. WILCOX-BUCHALLA: We do use targeted film checks to look at facilities where we have had complaints. There are a variety of reasons why you might do a site visit, why you may prefer to do clinical image review, and it is not always clear when you hear a complaint about clinical images, that it is not being impacted by other issues within that community.

So, we start with a clinical image review, but currently, unless there is some other evidence that there are significant problems, we would only ask for one set of films from one day, and I think you need to be careful about

issues of volume in mandating that it be more in a small facility, which may only do five to 10 patients in a day, and we want to look at normal films with very few exceptions, and it may be difficult to say we want to see two sets of normal films on a given day.

There are always exceptions, and I think leaving the latitude with the accreditation body to choose what is the best in a given circumstance, or to work with FDA or state inspectors about variety of issues on an individual circumstance, to leave latitude allows us to address the issue appropriately when it comes up.

DR. CARDENOSA: I would like to underscore Pam's comment about volume since there are some facilities that may not do a mammogram in a day, that may do two or three in a day, and so I think it is very important to be aware that there may be volume constraints on some facilities.

MS. HEINLEIN: Does it say anywhere in here that they are limited to only submitting one film? I mean right now the way it is written, the accrediting body does have that flexibility, right?

DR. BASSETT: Correct.

DR. FINDER: I just want to briefly say one thing. This discussion has already addressed GAO's points for the record.

MS. EDGERTON: I would just like the committee to know that not all accrediting bodies do it the same way. In fact, nobody else does it the way ACR does. California goes on site, and we have people pull films from a reasonable length of time. We pick that time. We tell them to put them in a positive pile and in a negative pile, and then we pull five images from the negative pile, and that is how we do our random.

I wouldn't want to use just one film from a facility. I will make a real quick point that comes later, but I don't think 3 percent either, when we get to the number, is enough. Currently, in the interim regs, we are supposed to do random clinical image review on every facility that we accredit in a three-year period, so that is third of our facilities every year, and that has changed drastically in the final regs.

DR. BASSETT: Trish, you mean if I decided to say that I thought Dr. Brenner's films weren't any good, and I called them and I said I don't think his films are any good because I just saw a case that came in, and this is my chance now to have him go through that, you would come down and make them put these things in stacks, and so on?

MS. EDGERTON: We assess complaints before we react.

DR. BASSETT: But I just wanted to clarify that, because it would depend on the nature of the complaint.

MS. EDGERTON: Yes, absolutely.

DR. BASSETT: And the flexibility should be left for the accrediting body probably, and it may not even be clinical images you want to look at, right? I mean it may be clinical images, fine, but one of the X-ray units is not working properly, and so on, so it is not just clinical images.

DR. PATTERSON: I just have a question to ask Trish. On those five that you are pulling up randomly, being that you are not doing the clinical image review, are you sending those five off to ACR for clinical image review?

MS. EDGERTON: Yes. The facility knows when we are on site that it is a random -- ACR knows that it is a random also, and I have been told by ACR that they are reviewed on a slightly less criteria, because they are coded. The reader knows that they are either targeted random for a facility that you think has a problem, or they are truly random. They actually make that distinction. So, there is three distinctions the reviewer has.

DR. BASSETT: Going back to the on-site visits now. We have slipped into the random clinical review, but just going back to the on-site visits, remember, this is

facilities where a team actually goes in and does an evaluation.

Getting to sample size, is says here that the question was at least 5 percent is in the law, but it should be no less than 5, and does not have to exceed 50. There were two that said 50 was too low, and three questioned whether it was an adequate sample, and one indicated they thought it favored the larger accrediting body, because 50 would be less than a percent, for that same percent, as a smaller coding body, and that another comment felt that the accrediting body should do at least one in every state or, if it was an accrediting body for a state, they should at least do one in every region, so there should be some geographic distribution.

Now, just to remember what we are talking about here on an on-site visit is a visit planned that could include or should include at least some clinical image review, a review of the audit processes that go on, the personnel qualifications, the equipment, and consumer complaint mechanism. So, that is an example of the kinds of things that would be looked at.

We just talked already about the selection of the clinical images during that on-site visit. It was indicated by one comment that they should be determined by the

accrediting body, and the reason for that I think is what I just mentioned, what if the problem isn't clinical images, those are fine, but the problem is more the personnel that are doing the exams, and so on.

Go to the next one.

MS. HEINLEIN: To address the concern about does maxing out the number of visits to 50, does that work to the advantage of a larger accrediting body, does the cost for those visits, is that passed on to whomever they are visiting, or is all of the cost of that -- it is averaged to what -- so, it is averaged out.

DR. BASSETT: I am not sure about that. Let me get clarification. Pam? Or do you know, Flo?

DR. HOUN: I had thought that the on-site visit was not charged by ACR.

DR. BASSETT: I know it is an expensive visit, because they send a physicist, they send a radiologist and a technologist. So, everything is a very thorough check.

MS. WILCOX-BUCHALLA: The question is charge for random on-site surveys? There is no charge for a random on-site survey. There is a separate process for facilities that have failed multiple times and want to be reinstated. That does incur the cost to do the visit, but there is no charge for a routine random.

DR. BASSETT: I was asking if we could get just a general idea of what the average on-site visit costs, since we are talking about cost.

MS. WILCOX-BUCHALLA: An average on-site visit generally costs about $3,000.

DR. CARDENOSA: That $3,000, is tha t per facility or per visit?

MS. WILCOX-BUCHALLA: Thank you for that clarification. Usually, when we do randoms, we try to do four sites within a two-day period, so that we can hit a sample within a community and do the most amount, so it is about $3,000 for a two-day visit including four sites, so if you averaged that out.

DR. BASSETT: You are talking about the transportation of the experts and all that stuff.

MS. WILCOX-BUCHALLA: Yes, the major expense is travel costs.

DR. PATTERSON: Repeat what you said, Pam, I am sorry.

MS. WILCOX-BUCHALLA: It is $3,000 to do two-day visits, which usually hits four sites depending on the geographic location. Now, when we did Wyoming, we could make one site, having reviewers out for two days. So, you can't just say it's 3,000 for every four sites.

DR. HOUN: And the fees or the costs are different for the different accreditation bodies, too. When Iowa and Arkansas do it, the cost is less for yours?

MS. PENTECOST: Lisa Pentecost, State of Arkansas. There is currently no charge for on-site visits in the State of Arkansas. We don't foresee doing that. We like to use this opportunity, when we visit our facilities, is validation and education, and we feel it is a service to the facility.

DR. BASSETT: That was the same then, because there was no cost also. We were talking about how much it costs to do it, not how much was being charged, I believe, and there was no charge from either. So, the on-site visit is free, and you get a lot of education, so we should all want one.

MS. KAUFMAN: Nothing is free.

DR. BASSETT: Nothing is free.

DR. HENDRICK: As a matter of information, when you send out an on-site visit team, who goes in Arkansas?

MS. PENTECOST: We do not have a team in the State of Arkansas that visits on site. We have a chairman of our Clinical Image Review Committee that goes along with a member of our accreditation program, usually two members.

For the most part, in our state, all of our random -- you know, we get confused when we speak about random on-site and on-site visits -- currently, we have had a third of our facilities have had on-site visits. Those were performed by a member of the accreditation program that did not inspect that facility as an MQSA inspector to keep down the possibility of conflict of interest.

MS. BUTLER: Is the chairman of the Clinical Image Review -- I assume that is the radiologist that is in charge of that group?

MS. PENTECOST: Yes, all of our clinical image reviewers are ABR certified radiologists, and he has been approved by the FDA to be our chairperson for our review committee.

MS. BUTLER: Does California handle it the same way? You sort of have a little different situation with the clinical image reviewers being ACR.

MS. EDGERTON: Yes, we do. We don't have clinical image review. I would like it. For the purpose of this, it would be very handy to have a group of radiologists who would accompany us on these visits. But currently, I go out with or a member of my staff goes out with the inspectors, and we review the facility and choose random clinical images

to be sent in to ACR. That is probably one reason why we choose more images.

I think if we ever had -- I don't know, we haven't had a situation yet where we have had to go over a facility and pull many, many films. I think if we had that, we would have to make some sort of arrangements.

DR. BASSETT: I think that gives us an idea of what is going on for the on-site visit.

Any other issues on that?

Okay. Now, on the clinical image review for random sample of facilities --

MS. KAUFMAN: I think there is one issue, because it seemed like there were a number of comments on the number of facilities that were going to get the on-site visit.

DR. BASSETT: Right.

MS. KAUFMAN: The regulation only requires five on-site visits.

DR. BASSETT: Well, is there a certain percent, though, as well? You couldn't do just five if you had a large number.

MR. SHOWALTER: The range was included to be sure that a very small accreditation body didn't visit only just one, but had to visit at least five, and that a very large

accreditation body would not have to visit the full 5 percent, but would have to visit at least 50.

MS. KAUFMAN: I know a number of the comments were concerned, and they felt that an accrediting body the size of ACR should have to do more than that. I am not sure that the people who made those comments realized what kind of costs might be incurred by the facilities to increase that number, but that was a number of comments.

DR. BASSETT: All the facilities would incur the cost, because it is absorbed by all of them.

MS. HEINLEIN: I think the way it is written covers both the smaller accrediting bodies and the larger accrediting bodies.

DR. BASSETT: I think we have also rehashed this before, so this was just additional comments on the same thing.

[Overhead.]

DR. BASSETT: Now, on (2), this is the random sample of facilities, and it was stated by one that 3 percent was not consistent with the statute. They interpret the statute that all should undergo random clinical image review every three years, and that is why I went to Bob and asked him if he had an idea that was what was intended in the law, and he told me no.

DR. PATTERSON: Unfortunately, as I read the enabling legislation, the random sample is related to clinical images, and not to facilities, according to my grammar, and I may be wrong.

DR. BASSETT: That is why I spent a lot of time trying to find out what the real intent was, because a lot of things here can be read a lot of different ways.

DR. PATTERSON: Right.

DR. BASSETT: I hope that I arrived at what I think the spirit was originally. I don't think there was an intent that every single facility from what I have heard from the people I have asked.

MR. SHOWALTER: I think that, indeed, you can read it in different ways, and what we are trying to figure out here from this meeting, as much as anything, is what is it that makes sense to accomplish the goals set out.

I think counsel is not likely to give us any absolute truth in terms of what the words mean, but we have to figure out what it is that makes sense from a programmatic point of view.

DR. HOUN: I would also like to ask, in terms of trying to assure women that accreditation standards for image quality are met within that three-year period, what is adequate. I mean they get annual inspections, but we know

inspections do not have a one-to-one correlation with how images are produced, and if images are where the rubber meets the road, what is acceptable from a public health point of view of protection and evaluation of clinical images for facilities?

DR. FINDER: I think the other thing is the point you bring up in the next comments is if you are going to decide that 100 percent is not the correct amount, is 3 percent the correct amount.

DR. BASSETT: There were five that recommended going from 3 percent to 5 percent, but I mean these are five comments out of -- how many comments did you get? They probably all didn't address this issue.

MR. SHOWALTER: About 8,000 total.

DR. PATTERSON: Can I ask Pam a question regarding on the random clinical images, in other words, you send in an image, what percentage of those presently are not passing, that would have failed?

MS. WILCOX-BUCHALLA: I don't have that data with me, Elizabeth, and I would be uncomfortable making a guess that would go into record. I would be happy to provide that information to the committee, but I don't want to make a guess. We were just rerunning those numbers in the last

week for the end of Calendar Year 1996, and I don't have that data.

DR. PATTERSON: Can you give -- sort of a general term -- a small amount, large amount?

MS. WILCOX-BUCHALLA: My estimate is that it is comparable to what we see on initial evaluation for accreditation. So, the initial deficiency, and if you look at accreditation programs outside of mammography, including College of Pathology and JACHO, you see that there is an ongoing learning curve, so this is not a surprise.

I think that the issue has to be continual education. Again, I am absolutely guessing, I have not looked at the current year's, and I think the impact of the legislation may have had an impact on that deficiency rate, and I think we need to look at that before it goes into record that they are the same.

DR. SMITH: I think the history is kind of instructive, because I think to me it suggests what FDA is going to have to do. Originally, there was this sense of, well, they are picking their best images, so you need to do this random image review, and then the sense then became one that it could be really incredibly burdensome, and also send the wrong signal.

So, the question then becomes if you do -- facilities know that they may get a letter requiring that they submit images on a random basis, and that provides additional safeguard, but an uncertain one, and one that you would not be able to know the benefit of until you evaluated over time.

The same is the case with the proportion, 3 percent, 5 percent, any of these percentages are arbitrary, and they have a profound bearing on the size of the accrediting body in terms of their costs.

But I don't think you are really going to know the impact of this review until you have done it for a while and until you see what the results are and whether facilities in the interim maintain the same quality or whether you observe the same quality that you do from the random checks that you do from the submissions of the applications, and I think this is the kind of thing that is going to have to be evaluated over time to determine. It is a quality control check.

DR. HOUN: I think maybe one approach may be to be careful about putting in writing, in law, what the percent is, when maybe it will evolve, such that maybe 3 percent may be too high at one point, where maybe it is too low at a different point, or with a different accreditation body.

DR. HENDRICK: Larry, are the clinical image reviewers given different criteria, or does the ACR use different criteria for the scores that are reported back to accept or not accept a random clinical image review?

DR. BASSETT: I think some of the clinical image reviewers have different responsibilities than others. So, I am going to have to ask Pam to give that, because I am not usually looking at the random sample, I am usually looking at the problems or third opinions, that kind of thing.

MS. WILCOX-BUCHALLA: Random clinical image review, the reviewers recognize that these are random images and that the facility has a limited population to choose from, that they don't have the same window looking at best films. However, there is also the recognition on the part of that reviewer that the impact of deficiencies is not the same.

So, there are two thought processes, and there is some subjectivity in that review process, then, that there is a deficiency, but they could not evaluate whether it was as a result of patient cooperation or habitus.

So, that is what the difference is in the review process. Does that answer your question?

DR. HENDRICK: In the instruction that is giv en, clinical image reviewers, are they instructed to evaluate

random images differently or is it through a letter or something that goes out?

MS. WILCOX-BUCHALLA: Just a very generic statement that this is a random film check, that it is not a submission of the best work that the facility does.

DR. HENDRICK: Okay. My understanding is that the random review also includes a phantom image, is that right?

MS. WILCOX-BUCHALLA: That is correct. The phantom image with dose and clinical images are from the same day. So, I think we are getting a good assessment of the ongoing ability of the technologist in the facility to perform work of the radiologist to choose or evaluate clinical image quality, and technical assessment of the unit at the same time.

DR. BASSETT: Any other comments? Marsha.

MS. OAKLEY: I just want to, you know, for a public comment in the record, to be sure that again, when all the decisions are being made and when we are looking at the percents, keep in mind again the person that is having that mammogram, and we keep repeating the same thing about being sure, that is so very important, that they are reviewed well, that the random samples are done.

MS. SCIAMMARELLA: I want to make a comment about the cooperation of the patient. We find out at one

institution what happens is the technologist cannot explain for the patient, because they cannot speak the same language. Maybe it could be simple, but this is serious some times.

DR. BASSETT: True. On the other hand, you can't explain to the patient that they are 80 years old, and therefore, you know, you can't make them stand up straight if they can't. That is what we are really talking about. We are not saying that the technologist shouldn't be taught how to get the most cooperation possible from the patient. We hope that happens, and that happens when you look at the images that are selected to be representative of their work. That, we know, that they have to do that, but there is no way to know, when you look at the image, what the condition of the patient was.

MS. SCIAMMARELLA: The other is the facility who deal with a lot of seniors.

DR. BASSETT: That is true.

MS. SCIAMMARELLA: When we say the identification of birth date --

DR. BASSETT: That is exactly why there are some arguments against random clinical image review, because it might be a disincentive to do those kinds of patients.

The other question was could this replace other requirements without reducing quality, in other words, could you stop doing some inspection things, could you not do other things, and I really think that what we have now is what we believe is the best combination, and maybe in the future, these things will change as we learn more, but right now I think it would be a mistake to substitute one part of the process for another personally, I mean all of our important components.

Does anybody disagree?

And we have no scientific evidence that that would work also.

Could an accrediting body doing inspection combine this with a clinical image review? I think we have heard that doesn't happen.

On-site inspection is checked on an accrediting body -- well, that is the same question, and I think we found that doesn't happen.

We already discussed that the random sample can't have the same criteria as the selected sample.

I think we have covered everything. Any other questions, comments?

DR. FINDER: Just one thing in terms of the on-site visit, and I think I brought this up once before, when, if ever, should the interpretations be evaluated?

DR. BASS ETT: I am going to have to ask what happens now in terms of interpretation. I will have to ask Pam again. When these radiologists go on site, do they evaluate interpretation, and then we will discuss when and if they should.

MS. WILCOX-BUCHALLA: In our routine on-site visit, as a part of the review of the outcome data, the radiologist does discuss interpretation for those films that are scored. It is not a part of the outcome of the on-site visit other than in a narrative advice to the facility, but it is looked at.

DR. BASSETT: I don't know if we can, at this point in time, with everything we have talked about over these three years, do more than that. With the current regulations, we would have to do what Charlie said would be the unthinkable.

DR. PATTERSON: Thank you, Larry. At this point, being as it is a few minutes after 12:00, shall we break for lunch now, and because I don't know if everybody has checked out of their room, but checkout time is technically 12

o'clock, and we will come back. Let's see if we can do lunch in an hour and return back at 1 o'clock and reconvene.

I think the people that have departed early have already departed. The remaining people have something like 5 o'clock flights, is that correct? Is there anybody who has a flight before 5 o'clock?

We ought to be able to wrap up and finish up by 3:15 or thereabouts this afternoon without a problem. So, we will reconvene at 1 o'clock.

[Whereupon, at 12:02 p.m., the proceedings were recessed, to be resumed at 1:00 p.m.]

AFTERNOON PROCEEDINGS

[1:30 p.m.]

DR. PATTERSON: We will reconvene. It is now 1:30. Hopefully, we can get the rest of this done in less than two hours.

We are now going to move to Cass' aspect on -- well, all of these million things, phantom image review, et cetera. This is all under Accreditation Body Standards starting on page 14896, and I guess it covers that up to 8, and then also 82 to 83, a number of little pieces here and there.

Accreditation Body Standards

MS. KAUFMAN: Elizabeth, you will be glad to know there were a number of sections. There weren't that many comments, though. It certainly isn't like what Rita had to work with.

[Overhead.]

MS. KAUFMAN: The first section that I had responsibility for was 900.4(d), which is Accreditation -- and all of my topics have to do with Accreditation Body Standards -- and it has to do with phantom image review, and I tried to make it big enough so you guys could read it, too.

The number at the beginning is the number of comments that we received, and essentially they are statements. So, one commenter -- and these are general comments -- said they wanted clarification on who makes the ultimate decisions on the phantom images and what their qualifications are.

Another comment said that they thought there was a conflict of interest for any accreditation body under the present design criteria for evaluation of phantom images.

One commenter said they support accrediting bodies spelling out requirements for adequate phantom image review, and one comment recommends removing the phantom image review from accrediting bodies altogether. They believed that the review by the medical physicist and during the routine inspection is sufficient, and that the accrediting bodies don't need to be reviewing phantom images at all.

[Overhead.]

MS. KAUFMAN: There was one commenter who said that phantom image scores should be averaged after review by two or more reviewers, and there were two commenters that said that because TLDs are used, there is no second chance, that regardless of the amount of care that they take in producing their phantom image, that problematic images could fail and result in a facility shutdown.

I think that was all. Is there another for phantom image review? I think that might have been it.

Does anyone have any comments on the comments on phantom image review?

Okay.

[Overhead.]

MS. KAUFMAN: The next section then on page 14896-97 is 900.4(e), which is reports of mammography equipment evaluation, surveys, and quality control.

I am sorry, we are still on phantom image. This is on requirements for the phantom image.

One person said that FDA should mandate that accrediting bodies accept use of other phantoms other than the present one, that they felt that the present one does not optimally simulate breast tissue.

One commenter supported this section as it was written, and one commenter said that all facilities and accrediting bodies should use the same phantom, which actually they do.

[Overhead.]

MS. KAUFMAN: The next section is scoring phantom images. There were nine commenters that said that more than one qualified individual should be scoring the phantom images. There was one commenter that said that all

accrediting bodies should use the same scoring procedure that could be spelled out in guidance. As far as I know, all the accrediting bodies are using the same scoring procedure.

There was one comment that FDA should seek industry input before instituting any changes to the phantom image review. Any comments so far? No comments on comments?

[Overhead.]

MS. KAUFMAN: The next section is phantom image reviewers, and one person felt that accrediting bodies should not have the option of different criteria for phantom image reviewers, and that all reviewers should meet the qualifications for medical physicist.

There were six comments who supported the regulations as they were written, and there was one comment that this entire section should be deleted and accrediting bodies should be able to set their own requirements with FDA approval for the phantom image reviewers.

Any comments? Ed.

DR. HENDRICK: Yes. My reading of this is that first comment that actually do have to be a qualified medical physicist under these provisions in mammography to

score the phantom unless the accreditation body gets a special approval from the FDA to do otherwise.

MS. KAUFMAN: I agree with that, that you either have to be an approved medical physicist or FDA can approve some alternative plan.

DR. HENDRICK: I was just curious on these programs that the state accreditation programs really don't have necessarily medical physicists scoring the phantoms, if that would automatically continue under these rules, or would they have to seek medical physicists who meet the credentials.

MR. SHOWALTER: I would not expect to see a change. All of the reviewers that I am aware of in the state accreditation programs have been trained in phantom image review typically in the inspection classes, either by you or by Bob Pizzutiello at this point.

DR. HENDRICK: But the way it reads, you would have to approve that as an alternate way to review phantoms under the new rules.

MR. SHOWALTER: Yes, that is correct.

MS. KAUFMAN: Any other comments?

[Overhead.]

MS. KAUFMAN: The next section has to do with image management, and this is phantom image management, by

accrediting bodies. Two commenters felt that the requirement to return phantom images increases costs without benefit, and one person felt that accrediting bodies should be allowed to retain the phantom images, so they can compare past and current images to look for changes, that might indicate changes in the quality control program.

They said that facilities in Arkansas have never requested return of the phantom images.

Anything on that?

[Overhead.]

MS. KAUFMAN: The next one is corrective measures for unsatisfactory phantom image quality. Six commenters supported this section as it was written as it provides assistance to the facility and assures timely correction of problems, and one commenter stated that the accrediting body has no direct authority to take appropriate action if corrective measures are not implemented.

[Overhead.]

MS. KAUFMAN: The next section probably had more comments, and it is on reports of mammo equipment evaluation, surveys, and quality control, and that was Section 900.4(e).

There was one comment that said requiring equipment evaluation only increases the cost of

installation, and does nothing to increase safety, that it should be deleted as it is a duplication of effort -- I am presuming they mean effort on the part of the X-ray serviceman -- and the facility should verify they have required quality assurance and that a medical physicist survey has been scheduled.

Four commenters felt that the medical physicist survey on new installations is critically important, and two commenters felt that the time limit for the survey submitted with the application should be changed to one year instead of the proposed no earlier than six months, so that a facility who is changing their accrediting body would not have to have two surveys done in one year. That did seem like kind of a reasonable request.

Anything on that? Ed.

DR. HENDRICK: I think a number of comments that were made to the effect of saying that the equipment evaluation should be done by a qualified medical physicist were addressing what is here and what is at the very end of the final rules that Penny discussed on Monday in the QC section.

I know I referenced both places, but my comments didn't get put here, and there were about 30 comments saying that this should be done by a qualified medical physicist.

MS. KAUFMAN: I have got that coming up.

DR. HENDRICK: I am sorry. Okay.

MS. KAUFMAN: It wasn't 30, but it was a lot. I couldn't find 30. They were kind of mixed in throughout the comments.

[Overhead.]

MS. KAUFMAN: Four said that equipment surveys should only be done by a qualified medical physicist. One specifically said not by a service engineer. Nine said the section should be deleted that says, "surveys be conducted no later than 14 months after the most recent prior survey."

I think during our April meeting that we all agreed, too, that that should be deleted.

One said that it was redundant for facilities to have to submit information to the accrediting body, that since they are inspected annually, and they may also receive an on-site visit by the accrediting body, that they didn't feel that they should have to submit this information to their accrediting body.

One suggested that if the medical physicist re port was not provided within 30 days, that all affected equipment should be removed from service, that the removal and reinstatement after the report has been received should be

documented, and precludes the potential of unsafe operations.

I only found like four, but I gather you found some more.

DR. HENDRICK: What I saying is -- I am not talking about surveys -- but the item called Equipment Evaluations, which is the preliminary survey that as the rules are written can be done by someone who is not a qualified medical physicist.

There were I counted up 30 comments back in what was tabulated, where equipment evaluations are mentioned under QC, saying specifically that this should be done by a qualified medical physicist, not by someone less qualified than that.

MS. KAUFMAN: I certainly agree with that. We talked about this at the April meeting, and the problem was the enacting legislation said that it didn't have to be done prior to accreditation to getting a provisional certificate.

MR. SHOWALTER: T o getting a provisional, that is correct, yes.

MS. KAUFMAN: That was the problem.

DR. HENDRICK: I am sorry. I don't follow the logic on that.

MR. SHOWALTER: The statute says that requiring a submission of a medical physics survey cannot be a requirement for getting a provisional certificate. So, what we were attempting to do was to get some kind of an evaluation in place for that equipment prior to use on patients.

Now, the accreditation, by the ACR at least, does require, as I understand it, a medical physics survey by a qualified medical physicist prior to usage on patients. Certainly, philosophically, we had no problem with that. I had no problem with that. That is the way I wrote the interim regulations.

It does create some timing issues for some facilities. It creates some dead time for machines. That is not necessarily bad. That is a consequence of it.

But we have gotten differing legal advice since the interim regulations went out, and this was an attempt to try to deal with that. Maybe it is not a very good solution, but that is why it was in there.

DR. HENDRICK: I think it is good except that almost anyone it appears can do it rather than somebody who can really help the site establish that the equipment is suitable for use on patients.

MS. KAUFMAN: In the enacting legislation that is under the section that says Provisional Certificate, and it says the applicant for a provisional certificate shall meet the requirements of various sections except providing information required by certain clauses, and one of those clauses is proof of on-site survey by qualified medical physicist.

But I have to say that personally, I think that they should have to have a survey by a qualified medical physicist before they be allowed to treat patients. I wouldn't want to be one of those first patients.

Penny.

MS. BUTLER: In experience during surveys, I tend to agree with using the term equipment evaluation rather than survey, and the reasons are if the facility is getting a new unit, for example, it is not necessary, and actually impossible, to do a full survey. You don't need to do the screen test over again, and it is very difficult the evaluate the facility's QC program on that unit if they haven't started using the unit yet.

MR. SHOWALTER: Exactly, and that is why I philosophically came up with a new term, and we wanted to limit exactly what it meant. It didn't mean a full survey.

MS. BUTLER: But we should go one step further by specifying as was suggested during the QC section, that the only one who is really qualified to do the equipment evaluation is the medical physicist.

MS. KAUFMAN: Ruth.

MS. McBURNEY: If the term is left "survey," then it does follow to that it has to be a qualified medical physicist, because the definition of survey means an on-site physics consultation and evaluation of a facility performed by a medical physicist, and the definition of medical physicist is someone who meets the qualifications in the personnel section.

MR. SHOWALTER: You are exactly right except that if you use the term "survey," you can't require it in that situation.

MS. KAUFMAN: Because the enacting legislation specifically uses the word "survey."

DR. HENDRICK: But there is this middle ground where you can call it an equipment evaluation. It doesn't include the full survey because you can't evaluate the ongoing QC because there isn't any when the equipment is new, but you could still require that it be done by a qualified medical physicist, couldn't you?

MR. SHOWALTER: I think so.

MS. KAUFMAN: I think we talked about this during April, and I think we had hoped to correct that problem under the quality assurance-general, where it says medical physicist, that we were going to add "to survey and evaluate mammography equipment," and that is the way we were going to try and get around it was we suggested the addition of that word "evaluate." That is on page 14881, in the middle column, (iii), where it is talking about medical physicist.

MR. SHOWALTER: I think we hear the sentiment of the committee, and that is certainly one solution.

[Overhead.]

MS. KAUFMAN: The next section was 900.4(h), which is reporting and recordkeeping for accrediting bodies. It is on page 14897-98. I didn't see any comments on that section.

Any comments on no comments?

[Overhead.]

MS. KAUFMAN: The next one was 900.4(i), which is accreditation body fees, and eight felt that the fees are unreasonable, particularly for small practices. One commenter agreed with the reasonable price structure and suggested charging facilities with more than one unit a slightly higher fee than those facilities having just one unit.

[Overhead.]

MS. KAUFMAN: The next one is 900.6, which is withdrawal of approval of an accrediting body, and I didn't see any comments on that section.

[Overhead.]

MS. KAUFMAN: The next one is 900.7, which is accreditation body hearings, and I did not see any comments on this section for accrediting bodies, but I did see a statement that the reviewer had put in that section, so I am putting it up here just to make sure it doesn't get lost. It was regarding a statement that if a facility that is denied accreditation is entitled to an appeals process from the accrediting body, and there were four commenters that said reopening a facility whose accreditation has lapsed appears to be difficult, but it doesn't really belong under this particular section. Since there were four commenters, I thought I would throw it in.

[Overhead.]

MS. KAUFMAN: 900.13, which is on page 14882, and that is revocation of accreditation, and revocation of accreditation body approval.

There was one commenter who supported this section as it was written. There was one who felt that the section is unclear and asked whether a facility is allowed to

conduct mammography without accreditation. I think the answer is no as far as I know.

One said that FDA certification should not continue at all after an accrediting body has revoked their accreditation.

[Overhead.]

MS. KAUFMAN: The next one is 900.14, which is the suspension or revocation of certificates, and obviously, these at the current time are certificates issued by FDA.

One supports the section as it is written. One recommends that this section be revised to include a provision for states being certifiers. One recommends a rewrite, saying has been guilty of misrepresentation in obtaining or retaining the certificate. I think this is one we had suggested in April, too.

One recommends "determines" be changed to "believes," and one said failing phantom images and lack of processor quality control over a period of time should be a severity level 1. I think what they meant by that is it should result in a suspension or revocation of a certificate.

[Overhead.]

MS. KAUFMAN: The last section is 900.15, which is appeals of adverse accreditation and certification decisions.

There was one commenter who felt that the title of this section should be changed to delete the word "certification," since certification is addressed in another section. Actually, when you read it, I think it is correct the way they presently have it.

One commenter was unclear as to whether a facility can submit additional information in the appeal, that the American College of Radiology does not consider additional information, and the appeal is based solely on the review of the original films submitted.

One commenter supported it as it is written, and one commenter does not believe that there is an appeal process for suspension or revocation of certificates, once the certificate is revoked, there is no appeal. That is not correct. There is always appeal, but that is what that person's comment was.

One commenter felt that a word should be added, "Upon learning that a facility has failed to become accredited or reaccredited," and we talked about that in April. I think we all agreed that that should be added.

There is one comment that said there should be a time frame for the appeal, but I wasn't clear whether they meant the appeal to the accrediting body or if they meant the appeal to FDA if the accrediting body denies, because if the accrediting body denies, the appeal to FDA has to be within 60 days. So, I wasn't quite clear exactly what they were asking about, but something about a time frame for the appeal.

Any comments? We should have done this one last night.

There were two questions that FDA raised. On phantom image review, it said several comments questioned the value of returning phantom images after they had been reviewed. Should this be a matter left up to the accreditation body policy except that all phantom images resulting in failure of accreditation shall be returned?

It sounds reasonable to me. Any thoughts? I think there seems to be a consensus on that one.

The last question was on reports of mammo equipment evaluation, surveys, and QC. Several comments were that by placing a 14-month time limit on annual surveys, we would be encouraging facilities to schedule the surveys at 14-month intervals rather than annually. Should this section be deleted?

I think in April, we kind of thought that it should. I know I think it should. I think if you put 14 months in the regs, it is going to be every 14 months.

MR. SHOWALTER: Indeed, I think we wrote that and published this, I think we now believe that it is probably not legal to do that --

MS. KAUFMAN: Oh, good.

MR. SHOWALTER: -- since the statute calls for an annual survey, that it is inappropriate to put what may be an administrative tolerance kind of requirement into a regulation.

MS. KAUFMAN: Sounds good. Penny.

MS. BUTLER: Charlie, does that still mean that -- you know, for most of your inspection criteria, there is a tolerance associated with some of the performance standards -- would you still have that type of tolerance in the inspection criteria?

MR. SHOWALTER: From year to year, we would, but we are also going to be considering trying to capture more than just last year's date of survey, so that we don't see this survey creep, and that while we would allow tolerance of 14 months from last year's survey to this year's survey, we would try to build in something that would assure that over time you weren't doing it 14 months every year.

MS. KAUFMAN: Anything else? Ed.

DR. HENDRICK: What would the language change be to deal with this? Instead of putting it every 14 months, would you just put it every 12 months?

MR. SHOWALTER: Well, we probably would not even have to address it, since it is addressed in the statute, probably just take that section out is my impression right now. We will have to look at that.

DR. HENDRICK: And this section is where?

MS. KAUFMAN: That was 14897 on the lefthand side, (i), such annual surveys be conducted no later than 14 months, but (2) says the accreditation body shall require that all facilities undergo an annual survey. So, they would just delete that (i).

MR. SHOWALTER: That (i) probably could go away without any adverse consequences.

DR. HENDRICK: Okay.

MS. KAUFMAN: Thank you.

DR. PATTERSON: Thank you.

We are moving right along. I think you almost got us back on time, not quite but almost.

The next section. Maria has grown a beard. It is now no longer dark, it's light. Unfortunately, she is not

here, so Al is going to lead us through this next section. We are talking about pages 14879 and 80.

Requirements for Certification

MR. VAN de GRICK: I was pressed into service this morning about 9 o'clock, so the slides were put together in something less than ideal circumstances.

[Overhead.]

MR. VAN de GRICK: The section on 900.10 should be easy to deal with. There were no comments. Any questions?

The good news is on 900.11, two comments agreed with or supported the section.

Let me preface these. I think a number of these comments were based upon misinterpretations of the regulations and the law, so they may seem to be a little bit off the wall.

For example, this one. One comment recommended inclusion of states as certifying bodies in this section of the regulation. Obviously, that is going to come under an entirely separate regulation because of its complexity.

Something -- and I don't have a number here -- something over three comments believed that facilities should be limited to one provisional and one 90-day extension.

One comment addressed the question of accreditation by another entity as designated by FDA, and I believe another one, as well. They believe that it is not authorized by the Act.

[Overhead.]

MR. VAN de GRICK: They asked under what circumstances would it be necessary, and comments said it should be deleted unless an urgent need can be demonstrated.

Any questions on this one?

900.11(a). One comment stated that certification should not preclude off-site reading of films. I am quite comfortable that it does not.

900.11(b)(2)(i). One comment supported use of provisional for new facilities and those that inadvertently expire. The law does not allow the latter.

900.22(b)(3)(i). One comment noted that FDA has evaluated requests for 90-day extensions, and asks if FDA intends to transfer this to the accreditation bodies.

Any questions on th at one?

[Overhead.]

MR. VAN de GRICK: 900.11(c). One comment feels revocation of certificates to be given to the accreditation bodies. That is again given to FDA under the law. We don't have any options on it.

Another supported FDA having full authority for such appeals. We thank you.

Three comments stated concern that one bad clinical image or actions of one employee could result in revocation and a two-year prohibition against doing mammography. That again I believe is one of those things that comes from an incomplete reading of the regulations or proposed regulations. Revocation is not the kind of thing that we take lightly or based on a single clinical image.

One comment requested review of this section. Cited a facility that had had its certificate revoked by FDA on the recommendations of an accreditation body.

There was another comment that alluded to something similar to this.

I don't know where the story came from or the rumor, but there have been no revocations of certification to date.

[Overhead.]

MR. VAN de GRICK: 911(c)(1)(ii).

One comment wants a new subsection to state reasons for provisional expiration.

911(c)(2)(iii) and (iv).

One comment was concerned about extending provisionals to facilities that have lapsed or lost

certification, and two comments recommended FDA emulate Massachusetts mammo regulations.

Any comments on either of those?

911(c)(4).

Six comments requested facilities that have corrected causes for loss of certification be allowed to apply for reinstatement immediately, and that the two-year penalty is excessive.

Again, I believe there is a misunderstanding. the two-year penalty only applies to revocation, and in fact, when facilities have completed corrective action plans, which is a part of the reinstatement process, they may again apply for reinstatement.

DR. HENDRICK: I am sorry to interrupt your progress here. I just don't understand these two comments recommended FDA emulate Massachusetts mammo regs. How is that relevant to that?

MR. VAN de GRICK : It's not. The comments were there. I just put them up on the board. I did not feel that we needed to go back and start over again.

[Overhead.]

MR. VAN de GRICK: One comment requested that the two-year provision upon revocation be deleted, and then 31

comments state that two years is excessive for facilities actively taking corrective action.

Again, I believe this is a misinterpretation. Facilities that are actively taking corrective action have not been revoked.

Ten comments stated that -- I hav e to ask the radiologists if they have this problem -- ten comments stated that this section is frightening to radiologists, asked who decides when voluntary action or lesser sanctions have proven ineffective, and asks if any third party reviews FDA decisions.

Are any of our radiologists frightened?

Any other questions for this one?

DR. LINVER: Yes. Clearly, some of the radiologists are frightened. I mean they wouldn't have written these in if they didn't feel this way. I think there is just a general concern in the radiologic community that somehow things can be misconstrued in such a fashion that it would result of inappropriate action being taken.

MR. VAN de GRICK: Charlie, would you want to address the question of revocation versus suspension a little bit?

MR. SHOWALTER: A little bit. The 31 comments that said that two years was excessive apparently had not

read the statute, which calls out the penalty, and so it doesn't much matter what we publish here, it is still a statutory penalty for revocation, which is one reason that we would take revocation extremely seriously.

Even in the case that has been alluded to here, I think, in L.A. County, where Cass had trouble with this facility for years, where finally enough information came to our attention that we did a suspension without a hearing, which meant they could no longer practice until they either resolved the situation or had their hearing and we got overruled at the hearing, none of that involved a revocation. So, there was not this two-year penalty.

It could have led to a revocation, but the suspension without a hearing apparently got the attention of the owner of the facility, and they decided to buy a new piece of equipment and apparently get their act together and attempt to practice in a way that Cass and we would like to see, and the accreditation body would like to see.

So, yes, the two-year penalty is severe, it would only be taken in the very rarest of cases where we could not get cooperation any other way, and in that case it is probably not inappropriate.

MR. VAN de GRICK: Any other questions?

This probably then puts us virtually back on schedule.

DR. PATTERSON: Very good. Thanks very much for filling in.

We are down I guess to the last section, which is Alternative Approaches.

Alternative Approaches

DR. SMITH: Penny and I have come up with some proposed alternative approaches that we would like to add.

[Overhead.]

DR. SMITH: We haven't rehearsed this, but in the spirit of spontaneity, we are going to try to work on this together.

In the beginning of the proposed final rules, there was a discussion of the intent to comply with Executive Order 12866, which requires federal agencies to identify and access alternative forms of regulation and where feasible specify performance objectives rather than specifying behavior and manner of compliance and to avoid duplication of regulations.

[Overhead.]

DR. SMITH: In response to overlapping functions for facilities, accreditation bodies, and the FDA, there were 14 total comments.

One supported the idea in general, which was essentially that is something that ought to be of concern. Three suggested that inspectors should review the medical physicist survey. One suggested that accrediting body review the medical physicist survey.

Two suggested that the accrediting body review personnel documentation. Two felt that the accrediting body and the inspector should share all the data. One felt that inspectors should eliminate duplication tests already done by the medical physicist. No one commented that there were no overlapping functions.

We thought that we could actually ask anybody if they could see a pattern in these, because we don't. I mean there is essentially a series of comments suggesting the possibility that some of the functions are indeed overlapping.

One thing that the proposed final rules highlighted, however, that some of these overlapping functions may actually be valuable to assure compliance.

So, I think that these particular comments need to be accepted in that spirit - are they truly overlapping functions or are they some people's sense that they have identified duplication, and in fact, that duplication may have a compliance value.

MS. BUTLER: I would just like to point out that these comments came out of the ERG report, and after reading a lot of the letters that fell into the other sections, a lot of additional comments were sort of included in the body of letters that had to do with other sections, and I saw a number of other comments that sort of fell into this category suggesting that the accrediting body review the personnel documentation instead of the inspectors.

So, that may be something that showed a little bit more of a pattern, and it may be something that I would like to get the committee's opinion on.

DR. SMITH: One thing we should add also, that some of those letters were from inspectors who felt that this role could be played by the accrediting body.

MS. BUTLER: There were also additional comments suggesting that the accrediting body rather than the inspector should review the medical physicist survey on an annual basis.

DR. SMITH: Cass.

MS. KAUFMAN: I was one inspector who felt that it would be appropriate for the accrediting body to review the personnel requirements. That seems like a real appropriate role for the accrediting body to do.

I think, though, that it is very important for the inspectors to review the medical physicist report during the survey for several reasons. One is it is a review of what the medical physicist does, and while you are on site, you can kind of verify the accuracy of their report, but it is also an opportunity for the inspector to compare the medical physicist results with their own results, so it is kind of a cross-check for them, as well, in terms of their own work.

So, I think it is a very good learning experience for both the inspector and the medical physicist to have th medical physicist report review during the inspection.

Lastly, when you are on site, and you are looking at the medical physicist report, I think you can make certain verifications and assure that certain things do correlate with what is actually taking place at the facility, so that you can verify that this report is indeed for this facility and this machine, and that kind of thing, and that sort of verification can only take place on site, it can't take place some thousands of miles away.

MS. BUTLER: Trisha Edgerton.

MS. EDGERTON: I would just let you know that in California, this is one of the bonuses of being a state. There are some things that are actually to our benefit. One is we have access to all the physician and technologist

certifications for the state, so we can see if they do qualify as are they in California, as have they submitted everything for the radiologist with ABR qualifications. We can just look that up.

In addition, we can look to see if technologists are ARTM or CRTM, which is the California Radiologic Technologists. We also have access to the inspection records, which is really helpful for us to get a better picture of what is really needed by a facility for corrective action, and we work very closely with the inspectors.

I can't imagine doing our job in a vacuum without that information.

DR. SMITH: Ed.

DR. HENDRICK: One of the areas of extreme redundancy is the review of technologist QC tests. The technologist does these tests. It is required that they be reviewed by the supervising interpreting physician, by the medical physicist, by the MQSA inspector, and parts of them by the accrediting body.

In addition, the MQSA inspector reviews the medical physicist's review of the technologist QC tests. At some point, the focus becomes records rather than quality of mammography, and it seems to me that there are multiple

reasons for citations within this reviews of records that don't really get at the issue of quality, that only get at the issue of recordkeeping in a very redundant manner.

That is one of my concerns in the whole inspection process -- well, in this whole redundancy of review process that incorporates the way the inspections are done, is that extreme redundancy with no subsequent obvious improvement in quality.

DR. SMITH: Cass.

MS. KAUFMAN: There certainly is some overlap and redundancy, but I think it is probably to the benefit of all parties involved. Just to give a couple of real quick examples is a very likely area, frequent area where we see problems, and the physicist report is in the area of the technologist quality control test, and the physicist just, you know, didn't notice it.

A lot of times I think the physicist are performing their evaluations or surveys during evening hours or weekends when the technologist isn't there, and so they may not be actually talking to the people involved, and so I think that there is some overlap, but at this point in time I think it probably is beneficial to all parties involved.

I think maybe as the years go by and people get more of the continuing education and everyone gets better trained that this could be an area to look at again.

DR. SMITH: Let me ask a question of both Ed and Cass. Is the review of these records, is the availability of these records key to understanding a problem that you observed during an inspection, or are you going to identify a problem that you otherwise wouldn't detect in the inspection from the review of the records?

MS. KAUFMAN: It depends what the problem is. Both scenarios can occur. For example, I mean on of the problems that we discovered, that the physicist had not noted, was a facility who had ordered one time of mammo film, the company sent the wrong film, and the facility just used that film and adjusted their quality control tests for that film, but it didn't work for what they were trying to use it for.

The physicist -- and I don't know why -- had not noticed it. I think he had not looked through the daily records and noticed when all of a sudden everything changed. So, that was something that we noticed by a review of records only. That wasn't a result of our own testing.

But then there are other things where you test it, and you determine it. For example, if there is a problem

with phototiming on the unit, that was working fine when the physicist was there nine months ago, maybe now we will notice it during our inspection.

DR. HENDRICK: I think having the records of the technologist available for the year is extremely valuable on site. I think that those records need to be reviewed by someone to make sure that the technologist is doing QC correctly and is taking action when things go out of control.

Even the example you gave, Cass. A citation that results because the physicist didn't review the QC records of the technologist correctly, so it is a review of the review that is generating the citation, and those kinds of citations don't necessarily lead to improvements in quality. I guess some do, maybe the example you gave, but some don't.

MS. KAUFMAN: I guess I am not sure if that was even a violation. It is not a violation for a physicist to miss something.

DR. HENDRICK: Well, for the boxes that aren't checked, it is Level III citation.

MS. KAUFMAN: Yes, but the physicist had checked all the boxes, and everything was fine and dandy.

DR. HENDRICK: The whole inspection process looks great, then, it is not even a citation, but there really is a fundamental problem.

MS. KAUFMAN: Can be.

DR. HENDRICK: And that is part of what I am getting at, and, in fact, I have heard of this at sites that now the focus of QC at sites is to make sure that all the documents are in order, so that you don't get these kinds of citations rather than making sure that the quality is as high as it can be, and sites where expert -- and this isn't me at all -- expert advisors to image quality have gone in and made suggestions, and the site says, well, we don't need to do that, we have passed our MQSA inspection.

So, the emphasis is misfocused on documentation of routine rather than really focusing on improving quality, and I see this redundancy of records checks as one of those kinds of misapplications of human resources, that should be focusing on improving the quality of mammography.

MS. BUTLER: I really have to agree with that on this regarding the section, and I think Cass brought up an example to something I haven't seen specifically that, but I have seen things like that, but the bottom line is that for the QC tests, my understanding of the inspection as far as issuing violations is that if all the boxes are checked, and

they do it, regardless of if the results are out of control, and they are still operating -- well, with the exception of the processor QC -- but for most of the tests, you know, like the film-screen contact, and things like that, as long as the box is checked, regardless of what they are seeing, it is just an evaluation of records and whether they are on hand or not. I am looking for the substance.

DR. HOUN: I think that in trying to balance getting physicists who are at different performance levels to do the test versus then asking the inspectors to not only see that they are doing it, but that they are done correctly, I mean I think that oversteps what you want an inspector to do in trying to achieve a balance.

You want to make sure they do the tests, they check a box saying they have done it. If they have done it incorrectly, I don't think you are recommending that then there should be an additional level for inspectors to check against. I think the compromise was to make sure that whatever is required, that the physicist do it, at least the do it, and if they are running into further problems, if the inspection can pick it through the minimal testing that we do there, that is one issue.

The other issue is whether -- you know, I think women need some assurance that a facility meets standards,

and there is not a perfect way to assure that, and I think as we go through the years of implementation, we are finding more and more facilities understand what is expected, but you are right, people can have a great inspection, but they don't understand image quality or they may have poor positioning compression, which is not evaluated on the imaging.

That is why continued effort, not just inspection only or FDA only, but from accreditation bodies, professional societies, to continually push the envelope on quality. We are bringing up the baseline, but we are out there. That is something that you are advancing in terms of what you are learning in science should be done as a model for maybe future regulation.

MS. KAUFMAN: Actually, Ed, you brought up something where I think the inspector is extremely helpful to the medical physicist because one of the things that we do during inspections is look to verify that they took corrective action on deficiencies that the medical physicist identified, and I think that is a real important role that we play, number one; and number two, is that we have the legal capability to require them to make corrections that the medical physicist doesn't have.

DR. SMITH: Ed.

DR. HENDRICK: I don't disagree with that at all. I think the inspection does add a level of assurance that problems identified in the medical physicist report do get dealt with.

The problem I have is this almost triply, quadruply redundant review of the records, which isn't really a part of the inspector making sure that the tests recommended by the medical physicist get done. That is a single review of the medical physicist report and the service records at the facility.

MS. BUTLER: Let me suggest this. One of our charges in looking at this section, one of the things that FDA was asking the public about, are there overlapping functions perhaps that something could be eliminated without losing the quality we are striving for.

Maybe we are looking at the wrong place then. I mean because we have got three entities evaluating the technologist QC test - the accreditation body, the inspectors, and the physicist. Perhaps this could be something that would be left out of the accreditation body evaluation to assist with that.

MS. SCIAMMARELLA: From the consumer perspective, in order to help the consumer, I mean what are the things that you think are important to improve the standards? They

need to be taken into consideration in inspection. That is not duplication. I know what you mean by paperwork. We go with the list, we check, and that is fine, and that is the paperwork who I think everybody find in bureaucracy could happen. I think it would be important to know what you think we need to eliminate.

DR. HENDRICK: I am not sure I can give a full answer to that, but I think what is important is that someone at that site is focusing on quality and encouraging or coercing the other people at that facility to also focus on quality. The sites that I see that are not good, that a woman would never want to go into for a mammogram, some of which are accredited and certified, are sites where the radiologist isn't really there, the technologist isn't really focused on any of the issues of quality, and the physicist is a phantom physicist who comes in, in the middle of the night, does their testing, collects their money, and leaves, and nobody is focusing on quality.

There are sites that are out there, that are accredited and certified, assuring women that they are doing a great job, that really aren't, and it is because no one is taking responsibility for the quality.

I think inspections can identify those sites. I don't know at what rate they really are, and I think it

would take some kind of completely different audit than exists in this system right now to really ferret out in those kinds of sites what is going to lead to an improvement in quality.

I mean I think that we need some kind of audit that supersedes all the paperwork stuff and really goes in and says, okay, here is the site, what kind of job are they doing, where is the system failing in terms of the physicist, the technologist, the inspection, and the accreditation body.

DR. SMITH: Florence, did you have a comment?

DR. HOUN: I think that the suggestions by the public in terms of looking at whether the physicist survey, the personnel records are an area where we don't have to duplicate reviews or try to minimize that, they are good suggestions that we can look at.

DR. SMITH: Let's summarize. It seems to me that there is a consensus that, much as the law requires, there is an attempt to minimize overlapping and duplicate activities to the extent that they become overly process focused as opposed to outcome focused.

There is a natural tendency I think in a program like this to become increasingly focused on meeting the letter of the law instead of the intent of the law.

So I think the comments, I think we had a very good discussion, and some guidance as to if there is an opportunity to shorten the duration of inspections to the extent that they may become in some areas overly focused on reviewing records as opposed to concentrating on quality is a good issue, but not at the expense of quality.

I also think that Ed's last point is a particularly good one, and it is an R & D issue for the program.

[Overhead.]

DR. SMITH: The next section focused on design and qualification-based standard versus performance standards and outcome measures for -- and this is in a number of different areas -- phantom image testing under mammography equipment and quality control. There were 18 total comments, 13 were negative, 3 were supportive, and 2 were poetic - phantoms shouldn't be overpriced.

Four comments stated that the proposal to replace all equipment and QC tests with a single daily phantom image test was absurd since results will not clearly point to the source of the problem including an inability to interpret the phantom test.

In general, comments that were even favorable about this idea did not support that it is even remotely

possible at this time. The one comment that was positive said that they should work together to develop a suitable phantom to be used in the daily system test, and it might specifically replace the daily processor QC test and the monthly phantom image QC test, but in general, this idea was really viewed as wishful thinking.

Penny.

MS. BUTLER: We discussed this in the QC section, and unless there is anything new, I think we can move on.

[Overhead.]

DR. SMITH: As for alternatives related to the repeat rate, there were 13 total, 12 negative, 1 positive. One comment, the repeat rate can't serve as an alternative since it would only identify problems long after they had occurred.

Another comment noted that the repeat rate is a function of decisions about film quality, since there are no standard criteria for rejecting a film, a good repeat rate can either represent either good quality or indifference to low quality.

Another comment, which some people highlighted, and another comment favored the alternative since the facility would adjust their system if a problem in the repeat ratio appeared.

Obviously, the negative comments are more in keeping with the actual mathematics of what the repeat rate can really mean.

Any comments?

[Overhead.]

DR. SMITH: Alternatives related to mammography personnel, the interpreting physician and the medical audit. There were six total comments, 11 negative. We basically derived a lot of negative comments out of a small number of comments.

This is a typo, and it seems to be a multiple typo. Let's trust the larger numbers.

Three options, actually four for regulations, applying to interpreting physicians' qualifications were proposed. They could simply be qualification-based criteria, such as training and experience requirements, medical outcome audits statistics bound by acceptable ranges, periodic proficiency testing or some combination of the above.

Eight letters that were really quite similar in stationery and content were opposed to the use of all three. In other words, they, in effect, had misunderstood the proposal as viewing these as options, and felt that they would be unduly costly.

One comment supported the medical audit, and recommended that the results be made public. One comment supported the development of performance standards, and one comment opposed asking practicing physicians to operate research facilities. Again, that was a comment opposed to the medical audit.

Any additional comments?

In addition to these, I mean there was a general critique that the using medical audit statistics would give very uneven indications of performance. The same statistics could be a measure of good performance or poor performance, and poorer performance on the medical audit statistics might not reveal that that performance was actually higher than a better statistic. So, in a sense it is really impractical at this time, and probably impractical forever.

[Overhead.]

DR. SMITH: With respect to using the positive predictive value, there were 25 total comments, of which 24 were negative and one was supportive. The negative comments generally asserted that this value was unworkable due to varying definitions based upon the definition of a false positive exam.

Varying factors contribute to positive predictive value and factors that can lead to the misinterpretation of positive predictive value.

Some cited the difficulty in acquiring data, so in a sense there was problems with actually calculating the statistics

The public's lack of ability to interpret positive predictive value, and there is a concern about making these data public. Public disclosure places facilities at risk, and calculating ppv will not change physicians' behavior. I thought the last one was interesting.

The one supportive comment said that the idea was theoretically sound, but impractical and expensive. So that is a quasi-supportive comment.

[Overhead.]

DR. SMITH: With respect to proficiency testing, there were 14 total comments; 4 were negative and 9 were supportive.

[Laughter.]

DR. SMITH: One was kind of false. Penny and I both did this addition, and we would like to submit Penny's calculations for the record.

Of the 9 supportive comments, 2 were generally supportive, and 7 felt that a proficiency test would be

useful in meeting the initial requirements, but were opposed to periodic testing.

Of the negative comments, one felt producing such a test would be problematic, one felt the medical audit already serves this purpose. Again, we have already spoken to that issue. Another was indignant at the prospect of proficiency testing since it was in their judgment unprecedented in medicine.

There were no comments about proficiency testing among those that were supportive, that favored periodic proficiency testing. In other words, they felt that a proficiency test was useful as an entry level requirement to determine competency in interpreting mammograms, but were very opposed to the idea that a radiologist who had met these requirements once would periodically have to submit to testing.

DR. CHRVALA: Just commenting on the last point where they said that they felt proficiency testing was unprecedented in medicine, they have been doing it with cervical screening for quite some time with quite good results, and both cytotechs and technologists are complying with routine proficiency testing.

DR. SMITH: This was a physician. They probably think that is fine for technologists, but they are not going to submit to it.

DR. CHRVALA: Could you go back to the one prior to this? I had a question, I think. I think a lot of the issues that were expressed in the negative comments could be dealt with via professional education and public education, so that we could use the data in a way that would be educational and would also improve the quality of mammography from where it is now in the future. So, just those two comments.

DR. SMITH: Larry.

DR. BASSETT: How are you defining a proficiency test?

DR. SMITH: It is listed in the Federal Register I am sure as a test that would measure the radiologist's ability to accurate interpret films.

DR. BASSETT: Then, every radiologist who takes the oral examination for certification takes a proficiency test in mammography as part of that examination. They also take questions on their written exam. They actually are asked to look at images and make diagnoses and answer questions during the other.

So, it must mean, then, one large kind of test you take and try to -- you have to pass so many of the answers, is that what you are talking about when you look at images?

DR. SMITH: The FDA is talking about an alternative to --

DR. BASSETT: I understand.

DR. SMITH: So, a proficiency test could be almost anything that the public or FDA conceives as an alternative to the existing requirements.

DR. BASSETT: Then, most have already taken a proficiency test, and so it is no unprecedented.

DR. SMITH: But the other thing, as an alternative, the proficiency test would have to supplant everything in including continuing requirements, so the argument in effect is set everything else aside, and what if radiologists, you know, just every couple of years come in, read 100 films, and demonstrate that they can perform.

That is where I think the idea of unprecedented comes in is from the standpoint that after that oral exam or passing that board certification, that a physician would periodically submit to a competency testing evaluation.

Carole, the other thing is that again it is hard to dismiss these comments in the context of what CMAP has accomplished. The problem I think is in the context of

small numbers and the swings and ranges that could trigger the --

DR. CHRVALA: Misleading data. I don't argue that, but I think the idea of proficiency testing for mammography is not unfeasible if you have a panel that comes together, partly because we did something like this in Colorado, and they had films with outcome data associated with it, and they reviewed those films, they got scored, and then they re-reviewed them, which is essentially a proficiency test, and they were willing to do that on a regular basis, the radiologists were.

DR. SMITH: Again, this is a review of public comments. Obviously, the College of Radiology and others at least feel investigating the possibility of proficiency testing is worthwhile.

[Overhead.]

DR. SMITH: Clinical image review for the radiologist technologist. There were 70 total comments; 68 were negative, 1 general, and 1 positive.

A number of comments felt this approach was redundant, it did not appear to be commenting on this as an alternative criteria. Again, this seemed to be a function of misreading the proposed final rules.

Nine noted that the accrediting body already reviews clinical images, and 12 noted that the supervising radiologist has the responsibility for assessing image quality.

Others felt that the required clinical image review and the qualification-based standard was adequate. This really was among the more dominant categories of comments. Others felt the approach would be impractical and too costly, and one positive comment felt the qualification-based requirements do not guarantee competence, and recommended clinical image review and biotechnologist repeat analysis, a combination of the two.

[Overhead.]

DR. SMITH: Proficiency testing and practical exam. There were 272 total comments; 252 were negative, 11 supportive, and 10 were other comments.

DR. BASSETT: It doesn't add up.

DR. SMITH: I know.

[Laughter.]

MR. SHOWALTER: The difference is he stopped worrying about it.

DR. SMITH: You know, you people have no sense of humor. We are just trying to do something to make this

really interesting and to make sure you are actually looking at our overheads.

Seventy-nine comments stated that the cost of proficiency testing is too high, and would raise the cost of mammography; 61 comments stated that proficiency testing of technologists cannot be conducted in a fair manner. They felt that the qualification-based criteria was sufficient.

Thirty-seven comments stated that technologists' performance was already evaluated by clinical image review and random clinical image review, in other words, issues that could be attributed to technologists would be in that context, and so they felt that this was redundant

Five comments supported the advance certification of mammography as important. Two comments supported seminars that evaluate technologists for clinical competency and mammography as a hands-on exercise that would serve this purpose.

One comment noted that if retesting was required for radiologic technologists, it should be required for interpreting physicians. This was the turn-about is fair play comment.

One comment noted that the ARD Medical Sonography Society had tried this and discontinued it as proving too costly.

I think this was the section where we received a number of identical letters, half of them without letterhead, because they were the technologists from the facility, and the other half, with letterhead, because they were the radiologists.

Any comments on this?

[Overhead.]

DR. SMITH: The mammography medical physicist and addition of a written exam along with the practical survey test.

We gave up on the math at this point. There are 16 total comments; 8 negative, 4 supportive, and 4 needed more clarification.

The ERG summary, which we found, having gone through all these letters, to really have been a pretty accurate summary of what we saw in those monstrous piles that we got, didn't catch everything in this particular instance, but I think this is really one of the rare exceptions.

One comment said I believe it is ill advised for the FDA to undertake any such examination, and rather that they should just rely on examinations in place, in other words, essentially, that those are sufficient, and they

doubt that the FDA could do a better job of identifying a qualified medical physicist.

Another commen t stated that a written exam for physicist is possible and would provide more consistency nationwide, but again questioned whether or not it would be worth the cost.

Any comments? Ed.

DR. HENDRICK: My question is I understand that to put this document out, the FDA had to come up with some alternative proposals. Is the FDA seriously considering any of those that were included in this document at this time?

MR. SHOWALTER: I don't believe that any of us think that it is feasible to do any of those at this time. I do think that there is some appeal to this approach in the longer term, but I think we are looking at a much longer term than we are talking about in terms of getting some final regulations out here.

I think there is a lot of work to be done and a lot of research to be done before one can realistically use this approach as a real approach.

DR. HOUN: I think that especially in the equipment section where if there could be performance-based standards, such as the goal is to image a microcalcification of such and such size, that that will allow all kinds of

technologies to develop without having to be so prescriptive and doing alternative standards and writing preamendments, but those kinds of things I guess from the committee discussion are not yet appropriate at this time.

DR. HENDRICK: I think that is right. I understand your goal. I just don't think we are quite there yet, or maybe more than just quite there. I don't think we are there yet.

DR. SMITH: We have some questions. We have tw o. The first one states many comments stated that the proposed rules are excessively burdensome and bureaucratic. What specific requirements can be deleted and still maintain adequate quality?

Why don't we just go around the room.

MS. McBURNEY: I think as we have gone through these comments, we have made recommendations to delete several sections, and I think that would probably be the extent of what we would recommend to delete.

DR. SMITH: I think it would probably be useful in the next release for the FDA to highlight the response to these comments in that context, in other words, the issue that some of these proposed rules were duplicative or burdensome or overly bureaucratic was heard, and this is

what the committee and the FDA determined could perhaps be set aside.

Ed.

DR. HENDRICK: I have difficulty in understanding the rules as they came out. Is the format of the publication and the presence of the alternative proposals in the next round of issue, which will be the final rules I assume, or in the draft of that, that hopefully, the Advisory Committee will see, will there be a different format without the alternative proposals, and in a more comprehensible structure?

MR. SHOWALTER: What I expect you to see in your review this spring, whenever that exactly is, is a contiguous document that starts at the beginning and goes to the end of all of the rules without all of the jumping around that was the case in this publication.

This was done for ease of review, quickness of review, and internally, and in the attempt to get the document into the Federal Register sooner than it otherwise would have gotten in there.

We have adopted a different strategy this time for internal review in terms of trying to get thing into people's hands and getting their agreement to review them piecemeal in order to try to meet this October deadline, so

we are not left with a piecemeal document, we will have a contiguous document. That is the plan.

DR. HENDRICK: Will there be a preamble and what will the nature of that be?

MR. SHOWALTER: There will be a preamble. There will not be a preamble associated with what you see, but when the document is published, there will be a preamble. It won't be finished by then. But the preamble will have to address all of the comments, probably not individually, but grouped, and it will certainly have to address in some way the alternative proposal. I don't know what that will be at this point, but it cannot go unaddressed.

DR. SMITH: The next question of these two is that some have advocated the increased use of performance-based standards believing them to be superior to the design-specific ones. Does the committee feel that performance-based requirements can be used to replace some of the proposed standards, and if so, which ones?

I think we have really had that discussion already.

Thank you.

DR. PATTERSON: Thank you, Bob, and Penny.

We are just about on time. We are doing very, very well.

Discussion of Summary Minutes

DR. PATTERSON: In your packets on the lefthand side was the summary minutes from the October 21st through the 23rd meeting.

Are there any deletions, corrections, editing, et cetera? Yes, Bob.

DR. SMITH: I just have one comment about those from the way I looked over them. The discussion about states as certifying agencies really included no comments from the committee, only the presenters, so no one reading those minutes could get any idea of any of the issues raised by the committee that were responded to by the guests from the states.

MR. SHOWALTER: We can go back and take another look at that.

DR. SMITH: I think it would be worthwhile because it is the thing that the person responded to the person that asked the question, but there is no question or summary of the issues that they raised.

DR. PATTERSON: You are talking about the July minutes.

DR. SMITH: Well, you said in the packet. They were in my packet.

DR. PATTERSON: I had specifically said October. Didn't we approve the July minutes? No, we did not. Okay. You are correct. I had started with October, I am sorry. I will get to the July in a moment or since we have already mentioned the July, are there any other comments about -- let's put it this way -- either of the two sets of summary minutes? Is that the only comment about July? What about October? Yes, Penny.

MS. BUTLER: Honestly, with all the other materials that I brought here to read today, albeit it wasn't the same mass that Rita had, I didn't have a chance to review them, and I will and submit my comments.

DR. PATTERSO N: I understand that. I had a box, too, so that is okay.

If there are any comments, deletions, or corrections, et cetera, just let us know and we will go back and look at those transcripts, and we will go back over July regarding your comment, Bob.

Any other comments about the minutes?

[No response.]

Future Meeting Plans

MR. SHOWALTER: It says here future meeting plans, and I can tell you only basically what I said yesterday when

we were talking about the definitions and stereotactic, and let me repeat that.

We are looking toward a meeting in the late spring, early summer. We hope that we will have time by then to have developed an approach to regulation of stereotactic. We hope that that approach will be based, in part at least, on the successful series of meetings that the ACR and the ACS are in the process of having.

Not knowing when there will be an outcome yet and what that outcome will be makes it a little bit tenuous for us to set any firm dates at this time. So, it may be that we need to send out some proposals a little bit later once both we get a clearer idea of when we will be prepared for a meeting, and once we have a clear idea of what the new membership on the committee is going to be.

DR. SMITH: There were just some questions for people who were rotating off or were scheduled to rotate off at this meeting in light of Dr. Friedman's comments.

How do they regard themselves in the meantime before they are able to see the final rules before interagency review in the late spring?

MR. SHOWALTER: We are going to have to do something, and I don't know yet what that something is, in order to extend their status as Special Government

Employees, everybody who is present, all the members and consultants present at this meeting.

So, whatever is the method chosen, we will work out a legitimate and legal way for all the members and consultants present at this meeting to be able to participate in that review that Dr. Friedman promised.

This, however, I expect to be the last meeting, the last meeting with the committee constituted as it was here, and at the next meeting, the current members, three-year members and two-year members and consultants will have rotated off, and a series of replacements will have been appointed by the next meeting.

So, the consistency between the meeting and the next meeting will be the original four-year appointees, and of course, there will be a new Executive Secretary at the next meeting.

DR. PATTERSON: Are there any other comments, questions, et cetera? Yes, Ruth.

MS. McBURNEY: I just want to say as one of the people rotating off, that I appreciate all the hard work and effort that FDA has put into these regulations and what a dedicated bunch of people they are.

[Applause.]

MR. SHOWALTER: Well, I want to say on behalf of FDA the same thing about the committee. I think this committee has demonstrated a remarkable dedication and a remarkable level of hard work and wisdom and expertise in helping us, and we appreciate it greatly.

DR. HOUN: And a lot of toleran ce.

[Applause.]

DR. PATTERSON: Yes, Rita.

MS. HEINLEIN: I just want to comment on what a tremendous hit Flo was at the breast conference in California last weekend -- well, three or four days ago -- when she actually stood up there in front of all of these technologists and gave out the phone number to her desk, but preceded it by saying, "My husband has this number, my baby sitter has this number, now you all have this number, but my inlaws don't have this number."

[Laughter.]

DR. PATTERSON: Yes, B ob.

DR. SMITH: I just want to follow up Rita's comment and say what a hit it was at a meeting I was at in Nashville, when Florence gave out her home number by mistake. I called it and got her answering machine, and thought what was she thinking about.

DR. PATTERSON: Any other comments?

Well, I would like to say two things. Number one, it has been a very enlightening experience. I don't think I have ever read the Federal Register as carefully or as often and understood as little as I have. I shouldn't say that, but you know what I mean over the past three years.

I would also like to thank all of the committee members that have worked very, very hard in this committee, and have most of the time made my job fairly easy. I put that "most" in quotes.

I would also like to thank, not only the Charlie's up here, and Flo, but all of the FDA people that sat out there and worked so hard behind the scenes, and et cetera.

The other people that I would like to give a hearty thanks to is the other individuals, the equipment people, the accrediting bodies who have sat through these long, very long meetings that we have had, and have been tolerant, and have been able to answer questions whenever we asked them, they stayed awake, and I would like us to give them a round of applause for the individuals that are sitting out there.

[Applause.]

DR. PATTERSON: Yes, Marsha.

MS. OAKLEY: I would like to have the opportunity on behalf of the National Breast Cancer Coalition to thank

the FDA for finding a place for a representative on this committee, and also, as one of the few people on this committee that does not make the circuit from one end of this country to the other on what seems to be a daily and monthly basis for the majority of you, I want to thank you for allowing me to participate, again representing thousands of consumers, and I want to thank you for your tolerance of people who have not always read regulations and spoken across the country, so I thank you.

DR. PATTERSON: And we thank you.

[Applause.]

DR. PATTERSON: Yes, Mike.

DR. LINVER: I also would like to give my thanks to everybody for a lot of hard work within and without the organization of the FDA, and all the membership here.

Toward that end, I have written another song -- that I will save for another occasion.

Thank you.

DR. PATTERSON: Again, I would sort of like to put this tongue in cheek. I would like to thank Mike for organizing all of those New Mexico radiologists who sent in those tons of letters. I didn't think there was that many radiologists there.

DR. LINVER: There are 87 radiologists in New Mexico. You received 114 letters. I had Bob check the map, so I know it is correct.

DR. PATTERSON: On that, I am going to adjourn the meeting.

[Whereupon, at 3:00 p.m., the proceedings were adjourned.]